PMRA ARLA

Pest Management Regulatory Agency

Annual Report 2003–2004

Our Mission

To protect human health and the environment by minimizing the risks associated with pest control products in an open and transparent manner, while enabling access to pest management tools, namely, these products and sustainable pest management strategies.

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Our Mandate

The PMRA's primary objective is to prevent unacceptable risks to people and the environment from the use of pest control products.

Our Mission

To protect human health and the environment by minimizing the risks associated with pest control products in an open and transparent manner, while enabling access to pest management tools, namely, these products and sustainable pest management strategies.

Our Vision

A regulatory agency widely respected in Canada and abroad for the quality, transparency and efficiency of its science-based decisions and its commitment to sustainable pest management.

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Message from the Executive Director

While PMRA has regularly reported through the normal channels in Health Canada to Parliament, in anticipation of the new *Pest Control Products Act*, this is the first annual report designed particularly to address the requirement of the new Act. It is patterned after the recently released Progress Report 1998–2003. Specifically, it provides a status report on the administration and enforcement of the Act with status on registrations—including pest control products that pose lower risks, re-evaluations, special reviews as well as performance standards. Moreover, this annual report presents on significant scientific developments relating to the evaluation of the health and environmental risks and the value of pest control products as well as the integration of those elements into decision-making.

In our first year of implementing the Agency's 2003 to 2008 Strategic Plan, we have continued to focus on the three key objectives:

> To protect human health and the environment from unacceptable risks associated with pest control products through the use of sound, progressive science, modern risk assessment and risk management approaches, and innovative approaches to sustainable pest management.
>
> To meet the needs of Canadians for a transparent and participatory regulatory process, for timely access to new, safer and effective pest control products, and for timely re-evaluation of registered products.
>
> To create a workplace of choice in which employees can make an effective contribution to the mandate of the Agency and in which financial resources are effectively managed.

December 2002 saw Royal Assent given to the new *Pest Control Products Act*. This legislation is the culmination of more than ten years of consultation, and provides the legislative authority to enhance health and environmental protection and meet the needs of growers and our partners in the pesticide sector. The legislation is key for the Agency to meet its commitment to protect human health and safety, while supporting best practices in Canadian and global pest management efforts.

In fiscal year 2003–2004, much attention has been given to implementing the new Act, so that it can be brought into force at the earliest opportunity. As well, our priority continues to be harmonizing our registration activities with our international counterparts. In addition, we continue to work to register and re-evaluate pest control products in a timely manner as well as to streamline and improve our internal processes.

As we strive to become more transparent, we are working with our stakeholders through the Pest Management Advisory Council, the Economic Management Advisory Committee and the Federal/Provincial/Territorial Committee on Pest Management and Pesticides to put in place approaches with their input. Collaborating with stakeholders is also a fundamental part of our work on promoting sustainable pest management.

I am pleased to say that there have been many impressive achievements in 2003–2004, including meeting performance standards, making substantial progress on regulationsfor the new Act and on re-evaluation, continuing to move forward on harmonization and sustainable pest management as well as improving linkages and communications with all stakeholders. These accomplishments are a tribute to the expertise and dedication of PMRA staff striving to meet the challenges of continuous improvement in the area of health and environmental protection in pesticide regulation that our stakeholders demand of us.

Wendy Sexsmith

A/Executive Director

1.0 Regulating Pesticides

The PMRA is responsible for protecting human health and the environment by minimizing the risks associated with pest control products in an open and transparent manner, while enabling access to pest management tools, namely, these products and sustainable pest management strategies.

The PMRA regulates pesticides imported, sold or used in Canada nationally under two major federal statutes: the *Pest Control Products Act* (PCPA) and Regulations, and the *Food and Drugs Act* and Regulations. The PCPA provides authority to regulate the use of substances that claim to have a pest control use. It also regulates substances contained in pest control products, such as formulants, adjuvants and contaminants. The PMRA, on behalf of the Minister of Health, administers the PCPA, registering pest control products, re-evaluating registered products, carrying out compliance activities and setting maximum residue limits (MRLs) under the *Food and Drugs Act*.

Pest control products differ from many other substances that enter the environment as they are not by-products of a process; they are released intentionally for a specific purpose. Although their biological effects are what make most pest control products valuable to society, these effects can also pose risks to human and environmental health. For this reason, the PCPA and related policies affecting pesticides recognize and consider the environmental risks in addition to the human health risks and value of each product.

Pest control products have been closely regulated for many years. Consolidation of pesticide regulatory activities within the PMRA in April 1995 as well as planned revisions under the new PCPA will continue to strengthen the life-cycle management of pest control products in Canada.

The goal of the pesticide regulatory system is not only to prevent unacceptable risks, but also to minimize all risks posed by pest control products. Risk-reduction efforts promote improvements in the handling and use of pesticides as well as optimal management of pest problems. In June 1992, the United Nations Conference on Environment and Development helped launch international risk reduction efforts and endorsed these plans as an important part of sustainable development.

Keeping the risks associated with pesticides to the lowest levels necessary to manage pest problems enhances sustainable pest management. The key is to provide health and environmental protection while maintaining the economic viability of users. Many countries find a systems approach, which considers all aspects of pesticides and all available ways to mitigate risks, to be the most successful.

The PMRA manages the risks associated with pesticide use through the following:

- carrying out a detailed health and environmental risk and value assessment, and setting conditions of registration for new products;

- proposing MRLs under the *Food and Drug Act* for pesticide levels in food commodities;
- re-evaluating products that are already on the market;
- monitoring compliance with conditions of registration;
- supporting the development of sustainable pest management strategies; and
- developing new policies and regulatory requirements that meet evolving science and international approaches to reduce pesticide risks.

Companies that wish to sell a pest control product in Canada must submit detailed information and data for evaluation by the PMRA. These companies provide all the scientific studies needed to determine if the product is acceptable in terms of safety, merit and value. Depending on the complexity of the submission, a complete evaluation can take from several weeks to over a year.

Before making a registration decision on a new pest control product, the PMRA conducts a comprehensive assessment of the risk and value specific to the proposed use. The value assessment considers whether the product contributes to pest management and whether the application rates are the lowest possible to effectively control the target pest. The risk assessment considers the inherent toxicity, the persistence and the bioaccumulative nature of the pest control product as well as the potential hazards, including the level of exposure to humans and the non-target environment. Exposure estimates are a key component of the risk assessment process. As pest control products are deliberately introduced into the environment at quantifiable rates, potential short-term impacts of environmental exposures can be closely estimated. For long-term environmental exposure, the PMRA consults all available data on persistence and bioaccumulation.

The assessment determines whether the product will be granted registration and allowed for sale and use in Canada or whether it will be rejected. Pest control products are registered only if the human health and environmental risks are acceptable and if the product is efficacious.

For registered products, ongoing surveillance, analysis and re-evaluation safeguard against possible environmental or health concerns, particularly with older products.

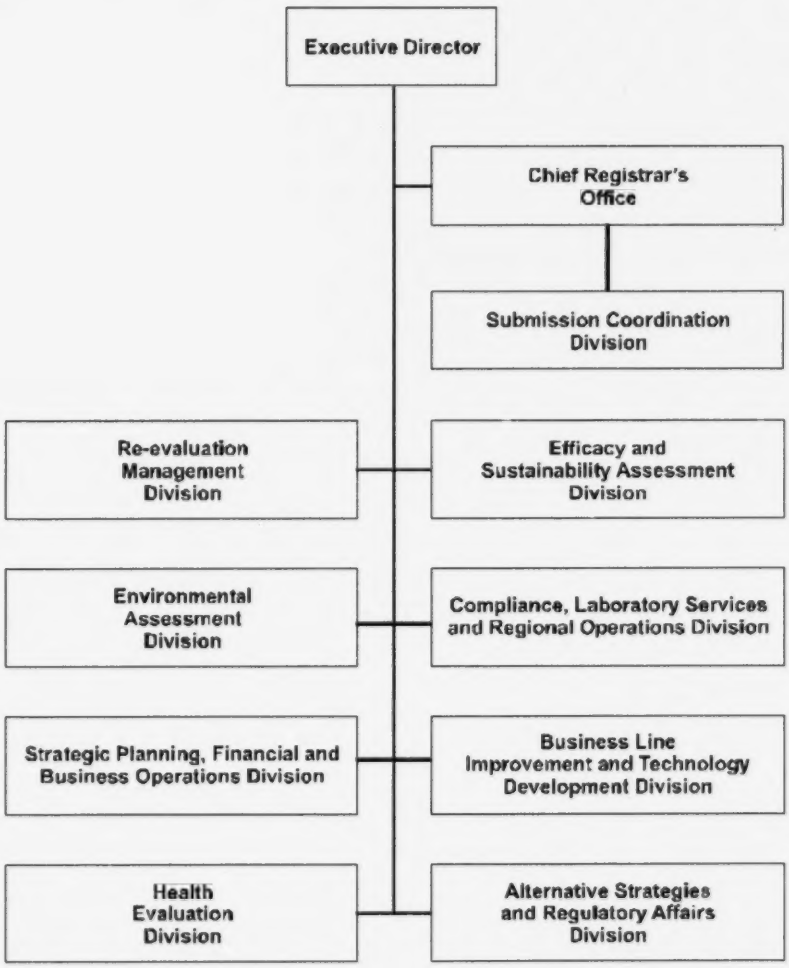
The Provincial/Territorial Role

Only pesticides that are registered for use under the PCPA may be imported into, sold in or used in Canada. The provinces and territories regulate the sale, use, storage, transportation and disposal of registered pesticides in their jurisdictions as long as the measures they adopt are consistent with any conditions, directions and limitations imposed under the PCPA. For example, a province or territory may prohibit the use of a registered pesticide in its jurisdiction or it may add more restrictive conditions on the use of a product than those established under the PCPA. It may not, however, authorize the use of a product that has not been approved under the PCPA and may not relieve the user of the obligation to comply with the conditions, directions and limitations imposed under the PCPA.

Provinces and territories administer a pesticide management program that includes education and training programs, the licencing and certification of applicators, vendors and growers as well as the issuing of permits for certain pesticide uses. Other important roles, often carried out in cooperation with PMRA regional offices, are those of enforcement and compliance monitoring as well as response to spills or accidents.

Provincial and territorial governments may also allow cities, towns and municipalities to enact bylaws to set further regulations on pesticide use, including use restrictions, based on local considerations.

2.0 Organization of the PMRA


Executive Director
Chief Registrar's Office
Submission Coordination Division
Re-evaluation Management Division
Efficacy and Sustainability Assessment Division
Environmental Assessment Division
Compliance, Laboratory Services and Regional Operations Division
Strategic Planning, Financial and Business Operations Division
Business Line Improvement and Technology Development Division
Health Evaluation Division
Alternative Strategies and Regulatory Affairs Division

As of 31 March 2004, the PMRA is organized as follows.

Executive Director's Office

- Oversees the operation of the PMRA
- Chairs the Agency Management Committee (AMC), comprising the directors of all divisions

Chief Registrar's Office

- Ensures the PMRA makes integrated, science-based decisions in a timely fashion and in a global environment
- Manages registration, including minor use, and product related issues
- Chairs Science Review Committee meetings
- Co-chairs, with an industry representative, the Economic Management Advisory Committee
- Provide secretariat support for external committees
- Provides policy and strategic advice

Submission Coordination Division

- Manages and tracks submissions
- Conducts scientific screening of submissions
- Manages databases
- Provides information services

Business Line Improvement and Technology Development Division

- Directs business line improvement projects, including electronic environment initiatives
- Provides information technology support

Efficacy and Sustainability Assessment Division

- Provides expertise on the use of antimicrobials, fungicides, herbicides, insecticides and other pesticides
- Houses a team of scientific evaluators that conducts efficacy assessments, sustainability evaluations and value assessments for pest control products

Health Evaluation Division

- Provides expertise on human health hazards, risk assessments and risk mitigation
- Houses a team of scientific evaluators that conducts toxicology evaluation and exposure assessment of pest control products
- Participates in national and international activities to harmonize testing and evaluation procedures

Environmental Assessment Division

- Provides expertise on environmental hazards, risk assessments and risk mitigation
- Houses a team of scientific evaluators that conducts assessments of the environmental fate and effects of pest control products
- Participates in national and international activities to harmonize testing and evaluation procedures

Alternative Strategies and Regulatory Affairs Division

- Develops policies, programs and projects related to sustainable pest management and coordinates national and international activities
- Directs the development, review and assessment of policies, regulations, programs and legislative amendments
- Liaises with other federal government departments through individual Memoranda of Understanding and with stakeholders through the Integrated Pest Management projects
- Co-chairs, with a provincial representative, the Federal/Provincial/Territorial (FPT) Committee on Pesticides and Pest Management
- Houses the Continuous Learning Program
- Prepares and implements strategic communications plans for the PMRA
- Publishes regulatory documents
- Handles Access to Information requests
- Manages the reference centre

Compliance, Laboratory Services and Regional Operations Division

- Enforces the PCPA
- Conducts national pesticide compliance inspections and investigations
- Represents the PMRA at the local level
- Provides expertise on the chemistry of pest control products and analytical testing
- Conducts product chemistry evaluations
- Conducts analytical testing of samples associated with investigation and inspection programs

Strategic Planning, Financial and Business Operations Division

- Manages the financial, human resource and business operations
- Coordinates the Agency's planning and accountability process
- Manages the integration of government initiatives such as modern comptrollership

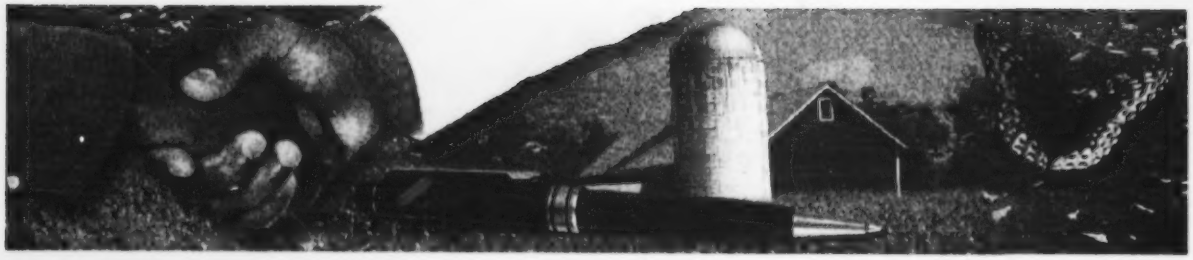
Re-evaluation Management Division

- Ensures the PMRA makes integrated, science-based decisions for older chemicals in a timely fashion and in a global environment
- Manages the re-evaluation program and issues
- Coordinates special reviews of specific aspects of the use of older pesticides when needed
- Chairs Re-evaluation Management Committee meetings
- Coordinates the Agency's re-evaluation activities with other countries to harmonize the timing and nature of decisions whenever possible
- Houses a team of scientific evaluators that specialize in the use of international reviews to re-evaluate Canadian products whenever possible

Of our 486 employees employed in the PMRA as of 1 April 2004, 331 are science professionals who evaluate every aspect of pest control products: from their chemistry, efficacy and health and environmental effects to their place in Canadian forestry, agricultural and domestic sectors. Our scientists are members of dozens of professional associations and institutes, and are recognized nationally and internationally as experts in their fields. They provide a wealth of experience in many disciplines, including human and environmental toxicology, biology, microbiology, chemistry, entomology, agronomy, parasitology, zoology, weed science, occupational hygiene and agriculture. Their research has been widely published in scientific journals and has garnered many awards.

Our support staff make the day-to-day operations of the Agency possible: managing communications, administrative services, training, human resources, financial administration and information systems.

The Agency's laboratory has been accredited by the Standards Council of Canada under stringent ISO/IEC 17025 requirements for the tenth consecutive year. The laboratory's high level of achievement has been recognized with two awards for excellence.



3.0 Regulating Pesticides with our Partners

International Cooperation

Pesticide regulatory agencies, growers and industry recognize that efficiency and effectiveness are maximized through international collaborative efforts.

The PMRA has worked closely for a number of years with two groups to advance international cooperation (harmonization) in pesticide regulation—the North American Free Trade Agreement Technical Working Group on Pesticides (NAFTA TWG) and the Organisation for Economic Co-operation and Development Working Group on Pesticides (OECD WGP).

Harmonization

Harmonization requires a complete understanding of the methods and practices used to regulate pesticides in other countries, and the willingness of everyone involved to merge these approaches. This does not mean setting standards to the lowest common denominator or simply accepting another country's decision, but rather finding an acceptable approach that respects and maintains or enhances our current high level of protection of human health and the environment. When an agreement cannot be reached, the differences are clearly defined. Canada is pursuing a wide range of initiatives with the United States Environmental Protection Agency (USEPA) and Mexico through the NAFTA TWG and with pesticide regulatory agencies in other countries through the OECD WGP.

The results of harmonization have provided the basis for a more efficient system that facilitates registration of safer and more effective pesticides, as well as the basis for promoting sound regulatory policies worldwide. Harmonization benefits everyone by increasing the use of work completed by other countries, thereby reducing the work of reviewing new and existing pesticides. Regulatory agencies see increased efficiency through work sharing initiatives and joint reviews. With their participation, the pesticide industry can benefit from faster and broader access to international markets. Growers in all countries have faster and more equitable access to a wider range of more effective pest control products, and public safety is enhanced as newer and safer products are introduced.

The goal of harmonization is to standardize the following:

- the type and scope of studies required to register or re-evaluate a pesticide;
- the protocols to be followed in carrying out these required studies;
- the format and presentation of manufacturers' submissions for registration (dossier);
- the formats for preparing and evaluating individual study reports (templates);
- the format for presenting of country reviews (monograph);
- the methods used to provide submissions and country reports (electronic tools); and
- the methods used to carry out risk assessments.

North American Free Trade Agreement

Under the North American Free Trade Agreement (NAFTA), the governments of Mexico, Canada and the United States formed the Technical Working Group on Pesticides in 1996 to develop a coordinated pesticides regulatory framework among NAFTA partners to address trade irritants, build national regulatory/scientific capacity, share the review burden as well as coordinate scientific and regulatory decisions on pesticides.

The Executive Board of the Technical Working Group is comprised of representatives of the member governments and meets twice a year to oversee existing and approved work. The Executive Board works closely with external stakeholders. National meetings with stakeholders are held annually, and the Executive Board meets with stakeholders from all three countries once a year. The governments carefully consider comments and recommendations from these meetings.

During the 2003–2004 fiscal year, the Executive Board met in July 2003 in Mexico City. The Canadian NAFTA Stakeholder meeting took place in October 2003 in Ottawa, while the meeting with stakeholders from all three countries took place in December 2003 in Vancouver.

An important accomplishment of the Technical Working Group was the development and finalization of a second five-year strategy (2003–2008) as well as an accompanying workplan. Stakeholders contributed in important ways to this accomplishment, both through their comments in national discussions and their active participation in NAFTA stakeholder meetings.

The *North American Free Trade Agreement Technical Working Group on Pesticides 5-Year Strategy* builds on the previous goals of making work sharing the way to do business and developing a North American market for pesticides, while maintaining current high levels of protection of public health and the environment and supporting the principles of sustainable pest management. The strategy outlines a vision: Canada, the United States and Mexico are striving to make the North American region a world model for common approaches to pesticide regulation and free trade in pesticides and food. Achieving this level of performance, while protecting human and environmental health, will set a global standard for and enhance world trade of North American products.

The responsibility for ensuring pesticides do not pose unreasonable risks to human health and the environment is shared by many, including governments, pesticide manufacturing companies, distributors, pest control operators, growers, workers, public interest groups and the general public. The Technical Working Group plans to take a holistic approach to pesticide management to create a high standard of excellence.

To realize this vision, the Technical Working Group will pursue the following three objectives over the next five years:

- full North American intergovernmental collaboration
- equal access to markets and pest control tools including lower-risk alternatives
- robust stakeholder participation

Specific projects that will contribute to achieving the goals outlined in this new five-year strategy are outlined in a companion workplan document entitled *North American Free Trade Agreement Technical Working Group on Pesticides Workplan*. In a number of cases, project tasks were completed during 2003–2004, thereby enabling joint activities to become a regular way of working together among NAFTA countries. Examples of these project tasks are as follows:

- The guidelines for pesticide resistance management labelling are being implemented through label statement review in Canada and the United States, contributing to sustainability.
- A set of electronic review templates for data evaluation reports have been completed and are posted on the PMRA and USEPA websites. These templates are now being used in the review of pesticide submissions, a further step towards harmonizing submission reviews.
- The electronic submission project, launched as pilot activity, has become an ongoing activity. The PMRA and the USEPA now encourage electronic submissions, given the improved efficiency when receiving and reviewing this type of submission.
- In addition, Agriculture and Agri-Food Canada (AAFC) and United States Depatment of Agriculture's Inter-Regional Project 4 (IR-4) have launched a pilot project to develop data and submissions for minor use applications, to be submitted to the PMRA and USEPA for joint review.

Descriptions of the status and accomplishments related to several other projects follow under Chapter 5, A Progressive Scientific Approach Towards Regulating Pesticides, and Chapter 8, Promoting Sustainable Pest Management. Joint Review activities are described in the Chapter 6, Evaluating Submissions, and re-evaluation activities in Chapter 7, Re-evaluating Registered Products.

Organisation for Economic Co-operation and Development

Thirty member countries meet through the Organisation for Economic Co-operation and Development Working Group on Pesticides (OECD WGP) to share the work of pesticide evaluation, to share information on risk reduction and to work together to harmonize approaches to the regulation of pesticides. Often building on NAFTA work, key accomplishments during 2003–2004 have been the initiation of the following:

- projects for harmonizing the use of study templates among countries and across different programs such as chemicals and pesticides; for developing test guideline residue chemistry including plant and animal metabolism, residues of concern and rotational crops; and for elaborating pesticide risk indicators;
- an analysis of differences in country risk assessments and how to resolve them; and
- the identification of key science issues to further the harmonization of biopesticides.

The PMRA remains actively involved, and the Acting Executive Director of the PMRA is the current chairperson, an elected position, of the OECD WGP.

In February 2004, the OECD WGP endorsed a 10-year vision for harmonization of regulatory approaches for agricultural pesticides to facilitate and promote the sharing of work between regulatory authorities. The vision consists of having the following elements in place by 2014:

- routine acceptance by OECD countries of dossiers (submissions) prepared in the OECD format;
- routine use of the OECD monograph format for country reviews; and
- routine acceptance of OECD monographs produced by other member countries as the basis for independent risk assessments and regulatory decisions for new and existing pesticides.

Critical to the success of this vision is industry participation.

Guidance on these formats may be found on the OECD website, on the EDDEnet website (Electronic Dossier, Delivery and Evaluation system) and through links via the PMRA website. The PMRA has been accepting submissions formatted in the OECD dossier format since 2000, producing reviews in the OECD monograph format (levels 1–4). The Agency is in the process of implementing the complete OECD Monograph format including Annexes A, B and C. Preparations are underway for a multistakeholder, OECD worksharing workshop to be held in early 2005 to examine further opportunities for worksharing and joint reviews among NAFTA, OECD and European Union countries.

To facilitate work sharing, it is also important to agree on standard templates for the individual studies submitted by pesticide manufacturers as well as for the Agency evaluation of these studies. The USEPA and the PMRA have developed standard templates for all scientific disciplines. Such templates lead to efficiencies by ensuring an adequate level of detail and predictability in placement of information. In February 2004, the OECD WGP implemented a project to harmonize the use of templates in OECD-member countries.

For several years, the PMRA has been using these templates as building blocks for risk assessments in the OECD monograph format and has been recommending their use to industry as the basis for their OECD dossiers. A leader in promoting the electronic submission and review of pesticide dossiers, in 2003–2004, the Agency worked closely with three Canadian registrants to prepare them for submitting fully electronic "pilot" submissions in March 2004.

The development of environmental exposure scenarios for non-agricultural pesticides such as biocides has been a priority activity in the OECD Biocides Task Force. During 2003–2004, the PMRA participated in the preparation of a draft OECD Exposure Scenario Document, *Harmonisation of Environmental Emission Scenarios: An Emission Scenario Document for Antifouling Products in OECD Countries*. This document provides a framework for general risk assessment of antifouling products for typical areas of exposure such as estuarine marinas, commercial harbours and shipping lanes. It takes into account the various stages of the life-cycle of antifouling products. Once finalized and accepted by the OECD, the antifouling Exposure Scenario Document will be a major achievement in the harmonization of environmental risk assessment approaches for non-agricultural pesticides. The PMRA will be applying the Exposure Scenario Document to develop scenarios representative of Canadian conditions and will be using these scenarios in conjunction with risk assessment tools, such as the recently developed aquatic exposure model MAM-PEC, to predict expected concentrations of antifoulants in Canadian waters.

In January 2004, the OECD published ENV/JM/MONO(2004)1, *Guidance for Information Requirements for Regulation of Invertebrates as Biological Control Agents (IBCAs)*. Implementation of the OECD guidance document into Canadian guidelines for the submission and review of IBCA products will require a multistakeholder consultation involving several government departments as well as IBCA producers, researchers and user groups.

Our Canadian Partners

The Pest Management Advisory Council

The Pest Management Advisory Council (PMAC), formed in 1998, serves as a forum to foster communication and dialogue among stakeholders and the PMRA as well as to provide advice to the Minister of Health on policies and issues relating to the federal pest management regulatory system. In order to achieve a balanced representation of interests in pest management issues, PMAC's membership includes environmental, health and consumer groups as well as academics and pesticide manufactures and users.

At its general meeting in June 2003, PMAC focussed its agenda on the implementation of the new *Pest Control Products Act*. Council members provided input to the proposals for new regulations that support the new Act, including the reporting of pesticide sales information, adverse effects reporting, WHMIS equivalency provisions, reconsideration of decisions and amendments to the existing regulations. In addition, the Council provided valuable advice on communication activities within the PMRA and helped to shape the look and feel of PMRA's annual report. More information on PMAC, including meeting reports, is available on the PMRA's website.

The Economic Management Advisory Committee

The Economic Management Advisory Committee (EMAC) was established in April 1997 to provide strategic advice to the PMRA's Executive Director on specific ways to improve efficiency and cost effectiveness, without compromising health or environmental protection and while maintaining industry competitiveness. EMAC membership includes pesticide industry representatives, grower groups and officials from the PMRA.

At its 26 November 2003 meeting, the Committee addressed many of the subjects on its workplan, such as the following:

- the PMRA's Re-evaluation Program, where possible, having decisions at or near the same time as the USEPA;
- PMRA's submission statistics with respect to the Management of Submissions Policy (MOSP);
- implementation plans for the new PCPA and proposed regulations;
- efforts to improve efficiency for Category C submissions to meet the MOSP performance standard;
- the Cost Recovery Evaluation Program; and
- the Financial Report: a summary of PMRA resources allocated by business line for fiscal years 1998–1999 to 2003–2004.

Various updates were also provided on the PMRA's Electronic Regulatory System project, OECD and NAFTA, the Globally Harmonized System of Classification and Labelling of Chemicals, the Formulants Program, minor use initiatives, labelling activities and the PMRA's recruitment plan. Additional information about EMAC is available on the PMRA's website.

Federal/Provincial/Territorial Committee on Pest Management and Pesticides

The Federal/Provincial/Territorial (FPT) Committee on Pest Management and Pesticides, formed in 1997, brings together provincial, territorial and federal representatives on pesticide use, regulation and management to exchange information and expertise. The FPT Committee working groups are addressing key pesticide issues: product classification, buffer zones, pesticide risk indicators, education training and

certification, drinking water monitoring and healthy lawns. In 2003–2004, the Committee addressed many of its priority issues, such as the following.

- A summary of stakeholder consultation of the proposed harmonized classification system. Implementation issues were broadly discussed and agreement reached that the Pest Management Regulatory Agency be requested to provide a formal response on implementation actions possible under federal authority to assist the CIWG in developing recommendations for a final harmonized system.
- Approval of the priority workplan, focussing on the National Standard, of the Working Group on Pesticide Education, Training and Certification.
- Accomplishments and plans of the Healthy Lawns Working Group.
- A training workshop for provinces on how buffer zones are established.
- Approval of terms of reference and a workplan for the National Pesticide Risk Indicator Working Group. The working group held a workshop for FPT Committee members on 23 October 2003 to discuss work that is underway on initiatives.
- Reports from the National Pesticide Sales Data Base Working Group regarding a meeting to discuss the approach to a regulation that would require reporting by registrants of pesticide sales data on an annual basis, and from the Drinking Water Monitoring Working Group regarding work towards a better understanding of existing monitoring programs for drinking water and sources of drinking water, and developing a more formal process to facilitate access to available monitoring data.

A stakeholder session was held prior to the FPT Committee meeting. Topics discussed by stakeholders included an overview of the role of other federal government departments in pest management and pesticides, progress on the pesticide industry's various stewardship programs as well their comments related to the new *Pest Control Products Act* regulations. Additional information about the FPT Committee is available on the PMRA's website.

Federal Partners

A number of departments are involved with pest management at the federal level. Relationships between the PMRA and federal colleagues have been described in various Memoranda of Understanding. Agreements exist with colleagues in other parts of Health Canada, with Environment Canada (EC), Fisheries and Oceans (DFO), Natural Resources Canada (NRCAN), the Canadian Food Inspection Agency (CFIA) as well as Agriculture and Agri-Food Canada (AAFC)

The ministers of Health and Agriculture signed a new Memorandum of Understanding (MOU) in December 2003. This MOU outlines the terms, roles and responsibility for AAFC and the PMRA respecting the management of the joint initiatives to achieve the following.

- Develop and implement commodity-based risk-reduction strategies for the agriculture and agri-food sector (see Chapter 8, Promoting Sustainable Pest Management).
- Improve access to agricultural minor-use pesticides and reduced-risk pesticides for agricultural use (see Chapter 6, Evaluating Submissions).
- Conduct research to support the introduction of minor-use pesticides that pose a reduced risk to the environment.

The MOU with Environment Canada was updated in 2003–2004 to recognize the provisions of new *Pest Control Products Act* the government investment in pesticide research and monitoring. It also recognizes

how the two organizations will cooperate and support each other in meeting their responsibilities in relation to environmental conservation, environmental protection and sustainable development as well as in other areas of mutual interest. New provisions include the sharing of information and the protection of that information, collaboration related to science on the presence, fate and impacts of pest control products in the environment, pest management strategies and pesticide risk reduction measures as well as the use by the PMRA of the results and conclusions of Environment Canada research, monitoring and surveillance activities. The MOU also includes provisions regarding the *Canadian Environmental Protection Act* and issues regarding pesticides and species at risk.

The federal Working Group on Pesticides and Pest Management has been formed to coordinate, promote and foster closer cooperation among the scientists and regulators working on pesticide and pest management issues at the participating federal departments—EC, DFO, NRCAN, CFIA, AAFC and Health Canada. This cooperation will allow for better, science-based decision making in the process of registering and managing pesticides. In 2003–2004, the working group:

- held a workshop for a number of government departments to assess research gaps and regulatory needs;
- made recommendations for additional research;
- developed and fostered relationships between regulators and researchers;
- promoted the exchange of information between the PMRA and other members regarding the PMRA's risk-based scientific evaluation for pest control products; and
- provided a mechanism to allow the PMRA to share research needs with other government departments and to select research projects for funding.

4.0 The New Pest Control Products Act

The new *Pest Control Products Act* (PCPA) was given Royal Assent on 12 December 2002. The new Act strengthens health and environmental protection provided by the existing PCPA, makes the registration system more transparent and strengthens post-registration controls on pesticides. The new PCPA also provides the solid legislative foundation needed to reduce risks posed by pesticides and to facilitate the availability of newer, safer products.

A phased approach for implementing the new PCPA has been adopted to enable the Act to come into force at the earliest possible date. New regulations are being developed to give effect to key provisions of the new Act (pesticide sales reporting, adverse effects reporting, providing material safety data sheets in workplaces, review panels for reconsideration of major registration decisions) and revisions to existing regulations are being proposed. Other important provisions for openness and transparency (public participation, access to test data in reading rooms), for which regulations are not required, will come into force with the proclamation of the Act. Areas requiring more lengthy policy development and stakeholder consultation, such as regulations respecting data protection, will be addressed in a second phase.

As proposed regulations are developed, they are published in the *Canada Gazette*. The *Canada Gazette* contains all formal public notices and official appointments, proposed regulations, regulations and public acts of Parliament from government departments and agencies. It serves as a consultative tool between the Government of Canada and Canadians by providing Canadians with the opportunity to provide their comments on proposed regulations found in *Canada Gazette*, Part I. *Canada Gazette*, Part II, contains all regulations that are enacted as well as other classes of statutory instruments such as orders in council, orders and proclamations.

New Regulations

Sales Information Reporting

The Pest Control Products Sales Information Reporting Regulations will specify requirements for recording, retaining and reporting sales of pest control products under the new Act. The sales information will facilitate priority setting, assessment and mitigation of health and environmental risks as well as tracking the effectiveness of risk reduction efforts.

Discussion Document DIS2003-04, *Preliminary Consultation on Proposed Sales Reporting Regulation*, was published for comments on 30 May 2003. Drafting instructions were prepared in the summer of 2003 and proposed regulations were prepublished for comments in *Canada Gazette*, Part I, on 27 March 2004.

Safety Information

The Pest Control Products Safety Information Regulations would specify the contents of Material Safety Data Sheets to be provided to workplaces under the new *Pest Control Products Act*. The safety information would provide improved decision making tools for pesticide workers and improved workplace safety through more complete information.

Discussion Document DIS2003-02, *Preliminary Consultation on a Proposal to Implement Elements of WHMIS for Pest Control Products*, was published for comments on 7 May 2003. Drafting instructions were prepared in the summer of 2003 and drafting of the proposed regulations is in progress.

Adverse Effects Reporting

The Pest Control Products Adverse Effects Reporting Regulations would specify types of information that must be reported by registrants/applicants under the new *Pest Control Products Act* and time frames for reporting. The adverse effects information would be used for re-evaluations and as possible trigger for special review, resulting in removal of pesticides and uses of unacceptable risk.

Discussion Document DIS2003-03, *Pesticides Adverse Effects Reporting Regulation*, was published for comments on 22 May 2003. Drafting instructions were prepared in the autumn of 2003 and drafting of the proposed regulations is in progress.

Review Panel

The new Act includes a process for the reconsideration of major registration decisions by a review panel. New regulations will provide for the establishing and functioning of review panels.

Discussion Document DIS2003-05, *Preliminary Consultation on a Regulation respecting Reconsideration of Registration Decisions*, was published for comments on 30 June 2003. Drafting of the regulations is in progress.

Revision of Current Regulations in Light of the New PCPA

Revisions to the Pest Control Product Regulations will ensure that terminology is consistent with the new Act and that any provisions that have been moved to the Act are deleted from the Regulations. Preparation of drafting instructions for the proposed revised regulations is in progress.

5.0 A Progressive Scientific Approach Towards Regulating Pesticides

Developments in Efficacy Assessment

Efficacy Guidelines for Plant Protection Products

Guidelines that outline the general requirements for conducting efficacy trials, describe procedures and criteria for efficacy data evaluation and provide guidance in developing rationales for reduced data requirements were published in Regulatory Directive DIR2003-04, *Efficacy Guidelines for Plant Protection Products*, on 5 December 2003.

These guidelines consist of general principles that apply to chemical control products for plant protection, which are now being implemented. Registrants use these guidelines to develop the efficacy data required for product registration. PMRA reviewers also refer to them on a regular basis when providing advice to registrants during presubmission consultations and when reviewing efficacy data in support of submissions to register new uses and new products.

Regulation of Pesticide Seed Treatment in Canada and the United States

Regulatory Directive DIR2003-02, *Harmonization of Regulation of Pesticide Seed Treatment in Canada and the United States*, published 11 April 2003, provides information on how seed treatment products are currently regulated in Canada and the United States. This document demonstrates the substantial degree of regulatory harmonization of pesticides used for seed treatment in the two countries.

Developments in Environment Assessment

Terrestrial Field Dissipation Studies

The PMRA and the USEPA have been collaborating on a guidance document detailing the conduct of terrestrial field dissipation studies to resolve differences between Canadian and American field study requirements. A special symposium entitled "Pesticide risk assessment: From a conceptual model to a

quantitative exposure model" was organized at the 227th American Chemical Society National Meeting, 28 March to 1 April 2004 in Anaheim, California. The PMRA and the USEPA jointly presented the outstanding issues and proposed solutions to the participants from industry, research and academic institutions as well as to other stakeholders. The PMRA and USEPA are close to resolving the last remaining issues, after which the guidance document will be finalized. The document will then be published in both Canada and the United States for public comment.

Probabilistic Environmental Risk Assessment

The PMRA continues to be involved as an invited panel member in the USEPA Science Advisory Panel meetings to discuss Tier II models for refined environmental assessments and to monitor USEPA's progress in the development of methods in this area. The most recent of these meetings, held in March 2004, focussed on revisions to the Tier II models for assessing acute effects in birds, and the proposed use of a USEPA-developed variable volume water model as the receiving water body scenario for surface water concentration estimation. The PMRA is building upon the experiences of the USEPA in refining its environmental risk assessment approaches, in particular in developing different exposure scenarios.

Environmental Chemistry and Fate Data Requirements

In October 2001, the PMRA published for consultation proposed changes to the PMRA's environmental chemistry and fate data requirements for conventional chemical pesticides used in Use-site Category 14, Terrestrial Food Crops. The Agency revised these requirements in light of comments received and further PMRA/USEPA harmonization efforts, and published them as a Regulatory Directive DIR2003-03, *Harmonization of Environmental Chemistry and Fate Data Requirements for Chemical Pesticides under NAFTA*, on 10 November 2003. The changes, while removing the last remaining differences between PMRA and USEPA data requirements in this area, are based in science, maintain the stringency of the environmental data requirements and do not effect the interpretation of the data with respect to environmental protection. These requirements are now being implemented and, as a result, registration data requirements and test guidelines for environmental chemistry and fate are essentially harmonized between Canada and the United States for conventional chemical pesticides used on terrestrial food crops.

Developments in Health Assessment

Harmonized Toxicology Testing Requirements—Food Use

The PMRA has been working with the USEPA to increase the harmonization of toxicology testing requirements for conventional pesticide products. PMRA progress is dependent on USEPA progress in revising their toxicology testing requirements. To facilitate future work on this project, the PMRA has continued in-house work in updating a pre-PMRA directive on guidelines for developing a pesticide toxicology database to reflect current scientific and operational practices. Publication of an updated directive is anticipated and will assist further in harmonization activities such as worksharing and joint reviews.

Cumulative Risk Assessment

The PMRA has continued to interact with the USEPA and other stakeholders to develop and to refine methods and models for aggregate and cumulative risk assessment. These methods and models are being further developed through actual use in the assessment of older pesticides.

The PMRA provided substantial comments to the USEPA during the development of the revised cumulative risk assessment for organophosphate pesticides and will continue to provide input as the USEPA moves towards finalising the cumulative risk assessment for organophosphate pesticides and initiates the development of a cumulative risk assessment for the *N-methyl* carbamate pesticides.

Specific activities in 2004–2004 included the following:

- participation in the International Life Science Institute (ILSI) sponsored Cumulative and Aggregate Risk Evaluation System (CARES) User Advisory Group and the ILSI Risk Assessment Methodologies Technical Committee;
- attendance at relevant USEPA Science Advisory Panel meetings on topics such as physiologically based pharmacokinetic modelling; and
- the ongoing collection and analysis of Canadian use information, water monitoring and other relevant data.

Acute Dietary Exposure

The Agency performs various types of risk assessments to evaluate the safety of pesticides in food, including analyses to determine the nature and the amounts of pesticides that people might be exposed to over a single day.

The safety standard is termed the threshold of concern and is defined as the threshold at which dietary exposure from aggregate food residues is considered safe. That is, the potential daily intake (PDI) at the 99.9th percentile compared with the acute reference dose is less than 100%, or stated another way, the threshold of concern is the point at which the aggregate exposure from food residues, at 99.9%, is equal to the acute reference dose.

This concept is the basis of Science Policy Notice SPN2003-01, *Choosing a Percentile of Acute Dietary Exposure as a Threshold of Concern*, released 28 July 2003. This Science Policy Notice describes the process used by PMRA scientists in dietary risk assessments and discusses how the PMRA generally applies the statutory safety standard to acute dietary risk assessments regarding pesticide residues in foods. This document reflects the USEPA's recent dietary risk assessment science policy/guidance paper, *Choosing a Percentile of Acute Dietary Exposure as a Threshold of Regulatory Concern*.

Nondetected/Nonquantified Pesticide Residues in Food

Pesticide manufacturers who request that the PMRA establish an MRL, whether on imported or domestic food commodities, are required to submit data on the level of pesticide residues that remain in or on food. Data on the levels of pesticide residues in food are also available from a number of other sources. Often, instrumentation in the laboratory is not able to detect any residue below the limit of detection. However, even though the laboratory instrumentation cannot detect a residue, a residue may be present at some level below the limit of detection, which may still present a potential concern to human health. The PMRA's goal is to make exposure and risk assessments as accurate and realistic as possible, while not underestimating exposure or risk, so that everyone is fully protected, including infants and children.

Science Policy Notice, SPN2003-02, *Assigning Values to Nondetected/Nonquantified Pesticide Residues in Food*, addresses the values the Agency should assign to nondetected/nonquantified pesticide residues in order to meet this goal. These values are an important criterion used in the determination of chronic and, especially, acute dietary risk assessments. In general, the PMRA recommends use of a value of one half the analytical

limit of detection (½ LOD), one half the limit of quantitation (½ LOQ), the (full) lower limit of method validation (LLMV), or true zero for these nondetected residues. This paper also describes PMRA's policy of performing a "sensitivity analysis" to determine the impact of using different assumptions on the PMRA's risk assessment for the pesticide under evaluation.

This document reflects the USEPA's recent dietary risk assessment science policy/guidance paper, *Choosing a Percentile of Acute Dietary Exposure as a Threshold of Regulatory Concern*.

Assessing Exposure from Pesticides in Food

The PMRA performs dietary risk assessments that include estimations of human exposure to pesticide residues in foods over a single day and over a lifetime. These estimates require the use of magnitude of residue data to calculate and quantify the degree to which humans will be exposed to residues from the use of pesticides approved for use in the registration and re-evaluation/special review programs.

Exposures are determined for general and regional populations as well as many subpopulations (infants, children, teenagers, adults, seniors, etc.), some of which may require magnitude of reside data for specialized foods. The use of a pesticide on food is only supported in Canada if the dietary risk assessments are acceptable.

Science Policy Notice SPN2003-03, *Assessing Exposure from Pesticides in Food: A User's Guide*, describes the processes used by PMRA scientists in dietary risk assessments to quantify the level of food residue exposures to consumers of all ages. The purpose of this user's guide is to provide a comprehensive discussion of guidance documents, policy documents and databases that provide detailed, specific "how-to" information on assessing exposure to pesticides from the foods that we eat.

The PMRA has used, to the greatest extent possible, the policy and guidance outlined in the USEPA document, *Available Information on Assessing Exposure from Pesticides in Food—A User's Guide*.

Aggregate Exposure and Risk Assessments

Significant scientific developments have been affecting how the PMRA performs aggregate risk assessments.

Aggregate exposure and risk assessments involve the analysis of exposure to a single chemical by multiple pathways and routes of exposure. The pathways of exposure considered in this general principles document include the potential for pesticide residues in food and in drinking water, as well as residues from pesticide use in residential, non-occupational environments. The pathway of exposure refers to how human behavioural patterns potentially interact with pesticides in the environment. All potential, relevant routes of exposure (oral, dermal or inhalation) and pathways (through food, drinking water and residential use) are analysed within an aggregate exposure assessment.

Science Policy Note SPN2003-04, *General Principles for Performing Aggregate Exposure and Risk Assessments*, reflects how these developments affect the PMRA. This document relies on background information from several USEPA publications, notably the *General Principles for Performing Aggregate Exposure and Risk Assessments*.

Refining Anticipated Residue Estimates

When performing dietary risk assessments, the PMRA requires pesticide residue and ancillary data to support the use of more refined "anticipated residues" in acute dietary probabilistic exposure assessments. These data can be readily applied to chronic exposure assessments as well.

Science Policy Note SPN2003-05, *Guidance for Refining Anticipated Residue Estimates for Use in Acute Dietary Probabilistic Risk Assessment*, provides guidance on the extent and quality of data that can be used to refine residue estimates for pesticides as well as explains when and how the PMRA may use these data. Such data can include information from cooking studies, processing studies and market basket surveys conducted on individual produce items. In addition, such data can include information from "bridging" studies used to support the use of typical application rates or residue decline data used to support the use of typical preharvest intervals in probabilistic risk assessments. This guidance also provides information on how risk mitigation activities (e.g., increasing preharvest intervals, lowering maximum label rates) can be considered in risk assessments and used to adjust MRL levels.

This guidance document reflects the USEPA's *Guidance for Refining Anticipated Residue Estimates for Use in Acute Dietary Probabilistic Risk Assessment.*

Cancer Policy

In 2003–2004, there was a significant focus on methods to address carcinogenic risk assessment for children, as the USEPA and the PMRA have differences of opinion in this area. To resolve the differences, the PMRA developed an approach for children's cancer risk assessment that was provided to the USEPA, which was also working on new cancer guidelines with supplemental guidance on children's cancer risk assessment. The USEPA held a Science Advisory Board (SAB) in May 2003 to obtain comments on their draft document "Supplemental Guidance for Assessing Cancer Susceptibility from Early-Life Exposure to Carcinogens" (February 2003), which included the PMRA approach. The SAB published its report in March 2004. The SAB supported the USEPA proposal and the principles suggested by PMRA. The PMRA is now awaiting the final version of the Supplemental Guidance and it is expected that a harmonized USEPA/PMRA cancer risk assessment methodology for children will be the result.

NAFTA Guidance for the Establishment of Pesticide Tolerances/MRLs for Imported Commodities

The NAFTA TWG is finalizing an initiative to develop common guidance, including data requirements and policy and procedures for the establishment of pesticide tolerances/MRLs on commodities imported into NAFTA countries. A common approach to data requirements for import tolerances will promote trade between North America and the rest of the world.

The draft NAFTA document *NAFTA Guidance Document on Data Requirements for Tolerances on Imported Commodities* was released for public comment in 2003 on the NAFTA pages of the PMRA and the USEPA websites. The document provides detailed guidance on data requirements that meet NAFTA standards for the establishment of pesticide import tolerances or MRLs in Canada, Mexico and the United States. The common set of data requirements will typically result in a reduced data set as well as more efficient and cost effective process for applicants to obtain import MRLs for North America, if submissions are made concurrently to the three countries. Comments have been received and are currently being analyzed with

the intent of incorporating them into the final guidance document, which will be released in the coming fiscal year. Upon completion, this initiative will contribute to harmonization of tolerances/MRL setting in each country.

0.1 PPM Maximum Residue Limit Policy

A significant number of comments were received following the publication of Discussion Document DIS2003-01, *Revocation of the 0.1 ppm General Maximum Residue Limit for Food Pesticide Residues [Regulation D.15.002(1)]*. While the comments were generally supportive of the proposed change to the *Food and Drugs Act* and Regulations, there were a number of detailed comments concerning the implementation of the proposal. The comments were reviewed during 2003–2004, and a detailed analysis has been initiated. Adoption of this proposal will bring Canadian regulatory practice in-line with world standards for setting MRLs.

Developments in the Assessment of Health and Environmental Risk

Formulants Program

To implement recommendations pertaining to formulants resulting from the Pesticide Registration Review (1990), the PMRA published Regulatory Directive DIR2004-01, in January 2004. The directive outlines how formulants are regulated in Canada. The overall goal of the Formulants Program is to phase out formulants of concern and replace them with safer alternatives. Prior to establishing the Formulants Program, the PMRA evaluated a pest control product as a whole, i.e., the mixture of the active ingredient and formulants. Now, the PMRA will also consider each individual formulant separately. This new approach to formulant assessment is more protective of human health and the environment. The program is substantially harmonized with USEPA policy on inert ingredients.

As part of the formulants program, the Agency has categorized formulants found in pest control products that are registered in Canada based on level of concern with respect to human health and the environment. The resulting five lists are similar in structure to the USEPA Lists of Inert Ingredients, i.e., they were developed using the same criteria as the USEPA, with some additional Canadian criteria resulting from legislative or policy requirements.

- List 1 includes formulants of toxicological concern (as on the current and previous USEPA Inert List 1), those meeting criteria of the federal Toxic Substances Management Policy and those subject to the Montreal Protocol on Substances that Deplete the Ozone Layer.
- List 2 contains formulants considered to be potentially toxic.
- List 3 contains formulants that do not meet criteria for the other lists.
- List 4A formulants are of minimal toxicologic concern.
- List 4B contains formulants of minimal concern under specific conditions of use.

New requirements under the Formulants Program are being phased in over a three-year period.

In January 2004, the PMRA also published Regulatory Note REG2004-01, *PMRA List of Formulants*. This list contains the name, CAS number and list categorization number for all formulants found in currently registered pest control products and will be updated on a regular basis. In order to compile an accurate list, the PMRA requested, received and processed updated information from registrants and manufacturers on approximately 1500 formulants.

The PMRA is currently preparing an industry guidance document on implementation of the Formulants Program. A regulatory proposal on the data requirements and assessment methodology for new formulants is being drafted for public comment.

Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Canada has worked with other countries to harmonize existing hazard communication systems for chemicals for over a decade. The new global system was adopted by the United Nations Economic and Social Council in July 2003. Many countries, including Canada, are beginning the task of harmonizing existing regulatory regimes within the GHS framework.

The GHS will affect the type of hazard symbols and hazard signal words on labels of chemical products. The goal is to harmonize, to the greatest extent possible, the hazard classification and labelling systems of the four federal regulatory sectors in Canada (WHMIS, consumer chemicals, pesticides, transport) and those of other countries. A situational analysis document, comparing the existing systems in Canada with the GHS, was published in September 2003. In October 2003, the four sectors hosted a GHS workshop in Toronto to identify issues of concern to stakeholders.

A multisectoral workplan was developed, involving technical discussions throughout 2004, decisions on how the regulatory systems will adopt the GHS in 2005–2006 and implementation by 2008. Consultations are now underway in each product sector, on issues that must be addressed for each hazard class. A working group for the pest control products sector met for the first time to confirm membership and the terms of reference on 17 February 2004. The working group, chaired by the PMRA, includes representation from the provinces, manufacturers, workers safety, users of pesticides and public interest associations.

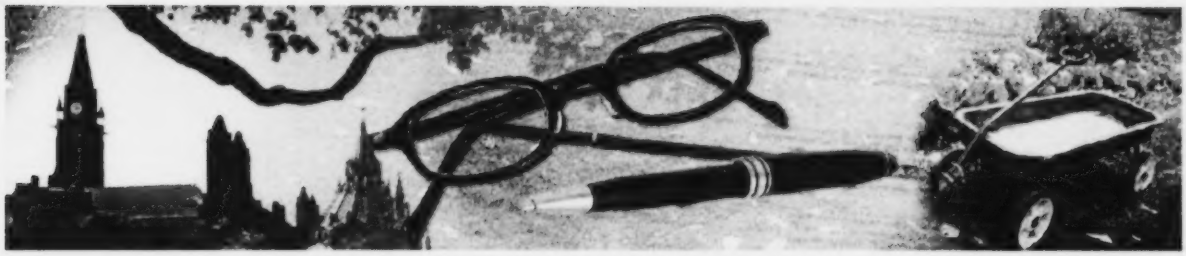
The GHS initiative is described in more detail at www.hc-sc.gc.ca/ahc-asc/intactiv/ghs-sgh/index_e.html.

Estimating Pesticide Concentrations in Water

Following the publication of Regulatory Proposal PRO2003-01, *Estimating the Water Component of a Dietary Exposure Assessment*, in March 2003, the PMRA completed consultation and is preparing to release the document as a Science Policy Notice in April 2004. The implementation of this policy will include the establishment of specific water modelling scenarios and processes.

The establishment of the physical parameters for a receiving water body based on various wetland data has reached a draft stage. Implementation of this scenario in estimating surface runoff for environmental assessment will be continued in the next fiscal year.

These activities have resulted in a significant advance for the PMRA in predicting pesticide concentrations in drinking water sources and other potentially vulnerable water bodies, leading to more refined health and environmental risk assessments.



6.0 Evaluating Submissions

Before a pesticide is considered for registration in Canada, it must undergo extensive testing to identify potential risks to human health and the environment as well as to demonstrate its value. The manufacturer must carry out the necessary scientific tests and studies before submitting data and results to the PMRA. The PMRA carefully reviews this information to determine if the product is acceptable for use in Canada. The Agency's decision to register a pest control product or to deny registration is based on an objective scientific assessment, using stringent scientific standards that are consistent with approaches used in other OECD-member countries.

The health, environmental and value assessments carried out by PMRA evaluators address the following:

- Where, how and by whom will the pest control product be used?
- What is its toxicity?
- Are there any potential health hazards to users or bystanders?
- Will our food and drinking water be affected?
- What is the impact on the terrestrial and aquatic environment?
- Is the product persistent?
- What is the value of the products?

The current approach to managing submissions, along with related performance standards, was introduced in 1996. The approach depends on applicants providing complete, good quality submissions and the PMRA examining these complete submissions within the stated performance standards. The responsibilities, timelines and performance standards were outlined in Regulatory Proposal PRO-9601, *Management of Submissions Policy* (MOSP) on 7 June 1996. Submissions were classified into a number of categories (A to E), as defined in Appendix I.

Presubmission Consultations

To ensure the most efficient use of evaluator time, data submissions must be complete. Accordingly, the Agency offers a presubmission consultation to applicants; this ensures they are familiar with the data requirements and minimizes the need to request additional data once the review begins. For products entering the Joint Review Program, the PMRA and the USEPA carry out joint presubmission consultations with the applicants from both countries. In addition, the PMRA regularly schedules a pesticide registration course to help registrants and other stakeholders understand the process of pesticide regulation in Canada as well as to understand how a submission should be put together.

A summary of presubmission consultations carried out in 2003–2004 appears in Table 1. Not all requests received during a year will be completed in that year as the request may have been received late in the year, for example.

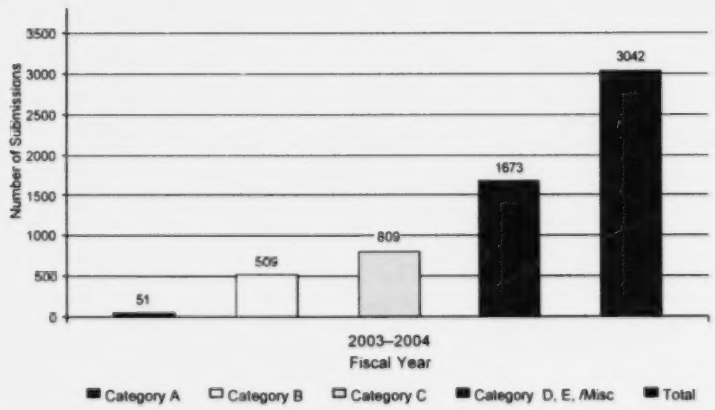
Table 1 Presubmission Consultations 2003–2004

Presubmission	Number of Presubmission Consultations		Number of Submissions Received Following a Presubmission Consultation
	Requested	Completed	
Conventional chemical	71	36	32
Biopesticide (microbial, pheromone, other biopesticide)	24	25	
Minor use (Category D3.1)	120	132	49

PMRA Workload—New Submissions

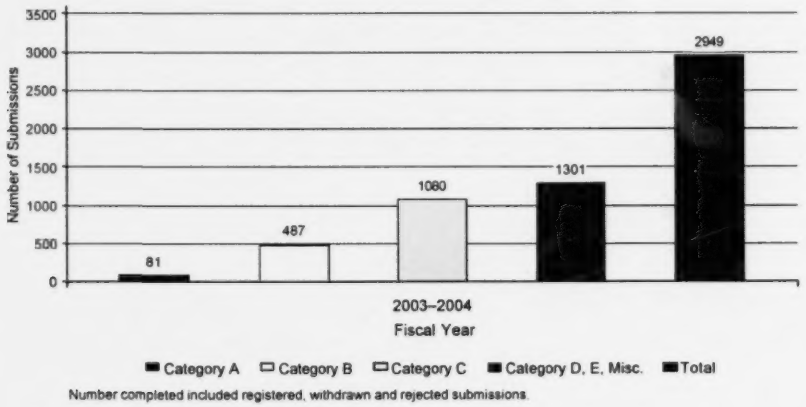
During fiscal year 2003–2004, PMRA received 3042 submissions (see Chart 1). This is slightly less than the 3222 submissions received in 2002–2003. Category A and B submissions accounted for about 19% of the total number, but represent the most complex evaluations and decision making.

Chart 1 Number of Submissions Received (2003–2004)



The Agency workload remained high, with over 2900 decisions made during the fiscal year. Chart 2 provides information concerning the number of submissions that were completed by the PMRA for the period 1 April 2003 to 31 March 2004. Completed submissions may be registered, withdrawn (generally requested by applicant) or rejected (a PMRA decision based on unacceptable risk or an incomplete database). An all time high number of Category A, B and C submissions were completed and registered during the fiscal year. The number of Category D submissions completed was lower than the previous year because of a delay in completing a number of renewal submissions before the end of the fiscal year.

Chart 2 Number of Submissions Completed (2003–2004)



Number completed included registered, withdrawn and rejected submissions.

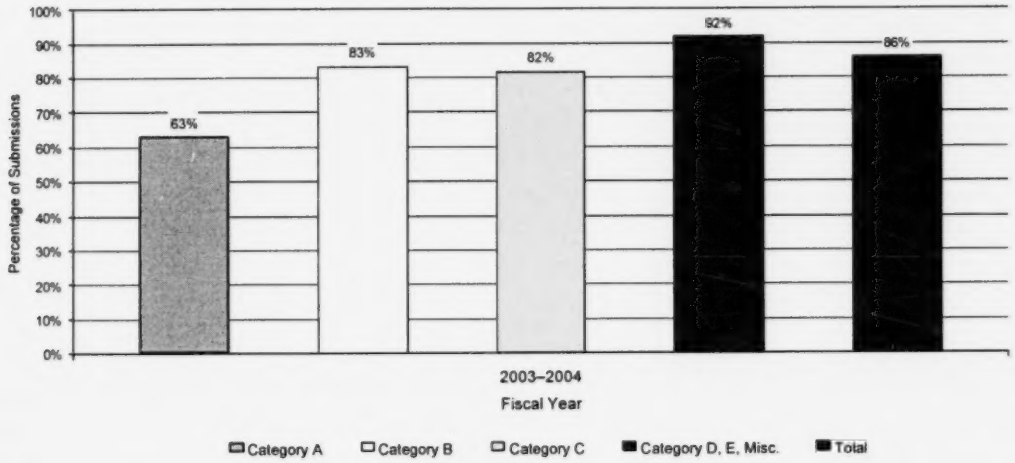
Six new reduced-risk chemicals and two new biopesticide active ingredients were registered.

Forty-four percent of new active ingredients registered in Canada in 2003–2004 were reduced-risk chemicals or biopesticides.

Twenty-eight percent of new active ingredients were registered via the joint review process. Three hundred and two minor crop uses were registered during the fiscal year.

Chart 3 illustrates the percentage of submissions completed that received a positive decision. Of the 2949 submissions completed, 86% or 2534 submissions received a positive decision.

Chart 3 Percentage of Submissions Completed that Received a Positive Decision (2003–2004)



Of the 81 Category A submissions that were completed in 2003–2004, 49 were registered. Two submissions for import MRLs were approved. The 49 Category A submissions that were registered contained 30 different active ingredients. Eighteen of the 30 active ingredients were "brand new" (that is, the active was found in a product first registered during that period). Included in the 18 are the two new chemicals in a new adjuvant. The other 12 active ingredients are found in other products that were registered before 1 April 2003. Appendix II summarizes key points about the new active ingredients registered in 2003–2004, while Appendix III provides a listing of the new active ingredients that were registered in 2003–2004.

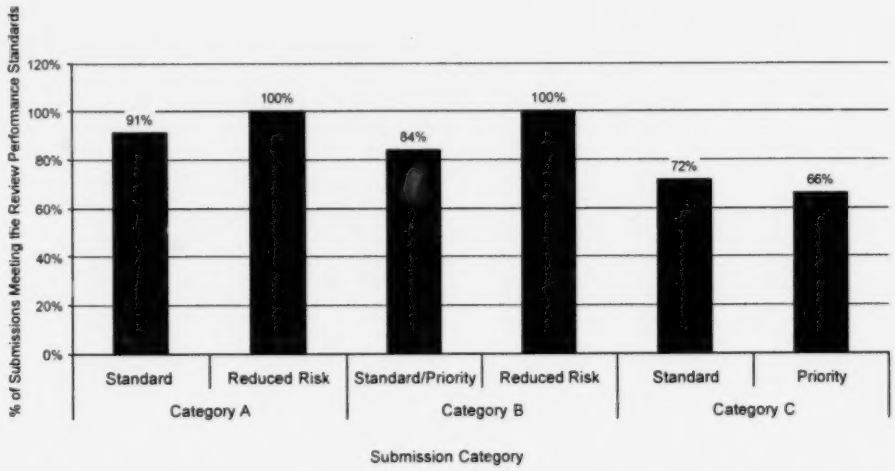
Submission Review Performance

The MOSP outlines the responsibilities, time lines and performance standards for the submission examination process. For the PMRA to meet the performance standard defined in the MOSP, 90% of the submissions in a given category must be completed within the stated review time. The PMRA has used the "review" stage (e.g., 550 calendar days or 18 months in the case of a Category A submission) of the examination process as the main basis for monitoring and reporting externally on performance. The review time does not start until the submission enters the review stage; at this point, the submission is considered complete and reviewable.

The PMRA's success in meeting the review performance standards for Category A, B and C submissions that were completed in fiscal year 2003–2004 is provided in Chart 4.

Chart 4 indicates that for standard Category A submissions (excluding those that had deviations from the MOSP), 91% of the submissions met the review performance standard of 18 months. See the Joint Review section for performance on joint review submissions.

Chart 4 Performance Against the Review Performance Standards for Category A, B and C Submissions Completed in 2003–2004



Category A Submissions

Category A submissions for new active ingredients and associated end-use products are often of the greatest interest to stakeholders. There were three main groupings of Category A submissions for performance reporting purposes in 2003–2004:

- standard Category A submissions with a review performance standard of 18 months;
- joint review submissions that had review performance standards ranging from 12 months or 18 months to negotiated review performance standards of 14.5 months and 28 months; and
- submissions completed under the new reduced-risk initiative review performance standards.

There were two Category A submissions (excluding those that had deviations) registered under the new reduced-risk initiative review performance standards. Both of the submissions met the six month review performance standard for straight chain lepidopteran pheromones.

Category B Submissions

There were two main groupings of Category B submissions for reporting purposes in 2003–2004:

- standard and priority Category B submissions with a review performance standard of 12 months; and
- submissions completed under the new reduced risk initiative review performance standards.

As indicated in Chart 4, 84% of the standard/priority Category B submissions (excluding those with deviations) met the 12 month review performance standard. To meet the 90% target, 25 additional submissions should have been reviewed in 365 days or less. These 25 submissions exceeded the 365 day review time by 10 to 72 days.

Three Category B submissions were completed under the review performance standards that are part of the new reduced-risk initiative. One of the three submissions was registered and the other two were withdrawn. All three submissions met the six month review performance standard for microbials.

Category C Submissions

There were two main groupings of Category C submissions for reporting purposes in 2003–2004:

- standard Category C submissions with a review performance standard of 180 days or a combined screening and review performance standard of 225 days; and
- priority Category C submissions with a review performance standard of 98 days.

Significant improvement in Category C performance was realized during the fiscal year. While the number of submissions received was similar to previous years, the number of submissions completed and registered reached an all time high. Review performance improved throughout the year on standard Category C submissions. In the first quarter the performance standard was met 59% of the time. This improved to 69% in the second quarter, 84% in the third quarter and 87% in the fourth quarter. The overall performance for the year on standard Category C submissions improved to 72%.

Performance on priority Category C submissions was 66%. Review performance has improved since the Regulatory Note REG2002-04, *Category C Submission Efficacy Reviews*, was published 31 July 2002. For priority Category C submissions that were received after the publication of the Regulatory Note and completed in 2003–2004, review performance improved to 82%. Submissions exceeded the 98 day performance standard by a maximum of 190 days.

Deviations

Unless indicated, the performance information includes submissions with deviations from the MOSP, that is submissions that do not follow the MOSP timelines for various reasons. Approved deviations for 2003–2004 are summarized in Table 2.

Table 2 Approved Deviations (2003–2004)

Submission Category	Number and % Completed Submissions with Deviations	Type of Deviation	Number and % Approved Deviations
Category A	36/81 (44%)	Joint review and related import MRL submissions	13 (36%)
		Applicant requested	6 (17%)
		PMRA proposed	12 (33%)
		Combined applicant request and PMRA proposed	5 (14%)
Category B	17/487(3%)	Applicant requested	6 (35%)
		PMRA proposed	11 (65%)
Category C	1/1080 (0%)	Applicant requested	1 (100%)

Most of the "PMRA proposed" deviations were to allow applicants an extra opportunity to provide additional data to complete the submission. In these cases, instead of requiring that the submission be withdrawn, the PMRA issued a second deficiency letter at one or more of the stages (e.g., screening or review) of the examination process. Other PMRA-initiated deviations were related to legal issues surrounding submissions and policy issues related to determining how to regulate a new use area.

Some submissions had more than one deviation. For example, on some submissions the applicants requested and were given extensions to their deadlines to provide a complete submission and later were given an extra chance to provide a complete submission. Deviations add time to the total life cycle time of a submission, but, in many cases, they also facilitate the eventual registration of products important to Canadians.

All of the joint review and related import MRL submissions had deviations from the MOSP. Most of the joint review and import MRL deviations were for negotiated review times longer than the normal 12 month review time. Two joint review submissions had deviations related to the extension of a deadline requested by an applicant.

Total Time to Registration

The average amount of time following the receipt of a pesticide submission that is required to reach a final decision on that submission is known as the average total time to registration. It is a measure of both PMRA and applicant performance.

The average total time to registration is made up of the following four component parts:

- average time for the PMRA to complete its steps (PMRA time);
- average time for applicants to address deficiencies (applicant time);
- average time for the PMRA to examine information related to deficiencies in a submission (deficiency time); and
- average public consultation time.

PMRA time consists of a verification step, a first screen, a preliminary review step, an evaluation step, the first decision and Proposed Regulatory Decision Document preparation, decision time after public consultation, and the first final-label review.

Applicant time includes all time that a submission is waiting for action by the applicant to respond to screening deficiencies, preliminary review deficiencies, evaluation deficiencies, final label deficiencies, missing fees, and the submission of final printed labels.

Deficiency time includes any extra cycles resulting from submission deficiencies, including additional screens, further preliminary review, additional review as well as decision times resulting from evaluation deficiencies and additional final label reviews.

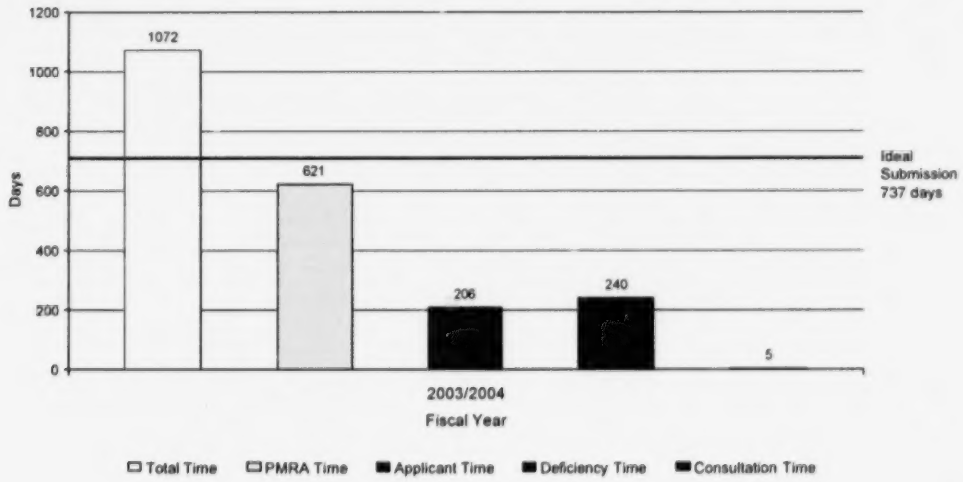
Public consultation time is the 45-day period allotted for public comment on a Proposed Regulatory Decision Document.

If submissions were ideal—that is, complete and had no deficiencies—and the PMRA met performance standards, the total time to registration would be the sum of the PMRA time and public consultation time.

Category A Submissions

Chart 5 shows the average times to registration for standard Category A submissions that were registered in 2003–2004. Thirty-three standard Category A submissions were registered, including two import MRL submissions. The combined average PMRA time and average public consultation times for standard Category A submissions continues to be shorter, at 521 days, than the expected 737 days for an ideal standard Category A submission. Had the submissions been complete, average times to registration would have been much shorter. Unfortunately, none of the standard Category A submissions met the criteria for an ideal submission.

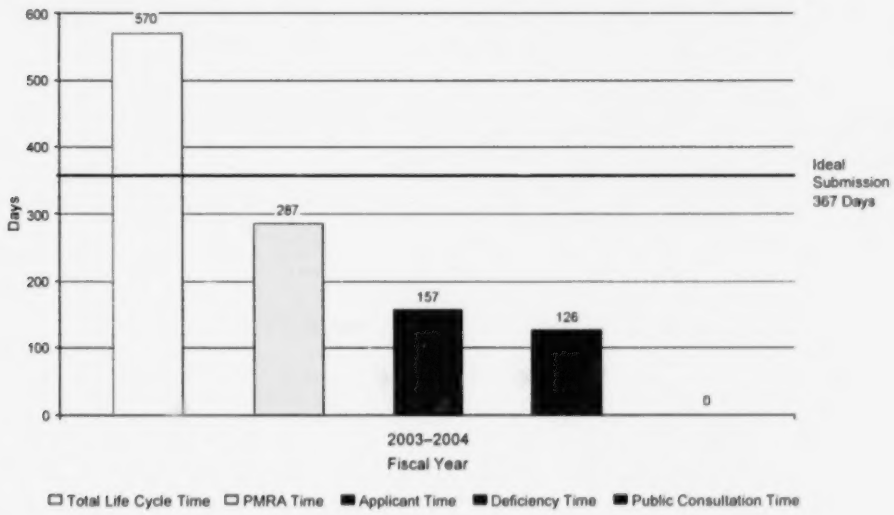
Chart 5 Standard Category A Submissions Subject to the MOSP: Average Times to Registration (Including Deviations)



The average total time to registration was 1072 days and the average PMRA time was 621 days. The difference between these two numbers is mainly attributable to applicant time, which on average was 206 days, and deficiency time, which on average was 240 days.

Chart 6 shows the actual times to registration for two standard Category A reduced-risk submissions for pheromones. The total time to registration was 570 days. The PMRA time of 287 days compares favourably with the expected ideal time of 367 days. The applicant took 157 days to provide corrected or missing information, and the PMRA used an additional 126 days (deficiency time) to examine the additional information provided by the applicant.

Chart 6 Two Standard Category A Reduced-Risk Straight Chain Lepidopteran Pheromone (SCLP) Submissions with Ideal Time of 367 Days: Average Times to Registration



Category B Submissions

Chart 7 shows the average times to registration for the 404 Category B submissions that were registered in 2003–2004. These submissions had a review performance standard of 365 days and an expected ideal time of 552 days. The average total time to registration of 419 days was shorter than the ideal time. The average PMRA time of 315 days is much shorter than the ideal time. On average, applicants needed 53 days to provide corrected or missing information, and the PMRA required an additional 50 days (deficiency time) to examine this information.

Chart 7 Category B Submissions Subject to the MOSP: Average Times to Registration

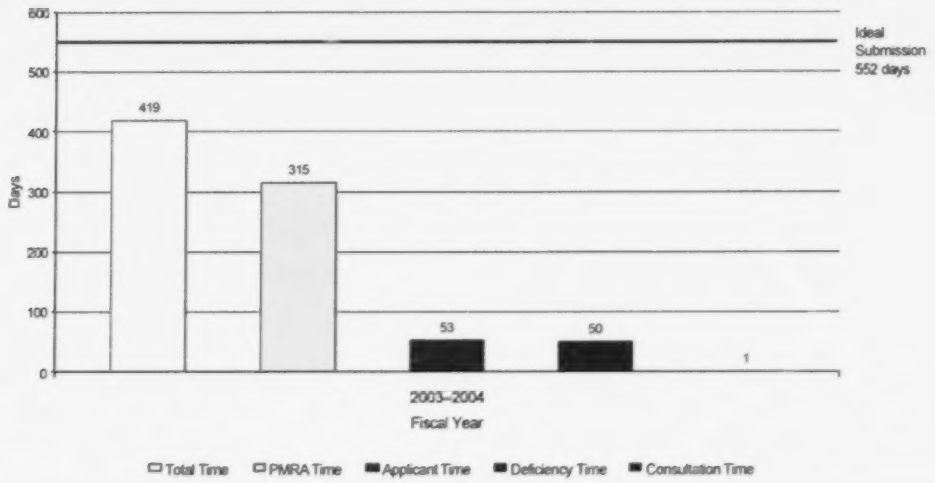
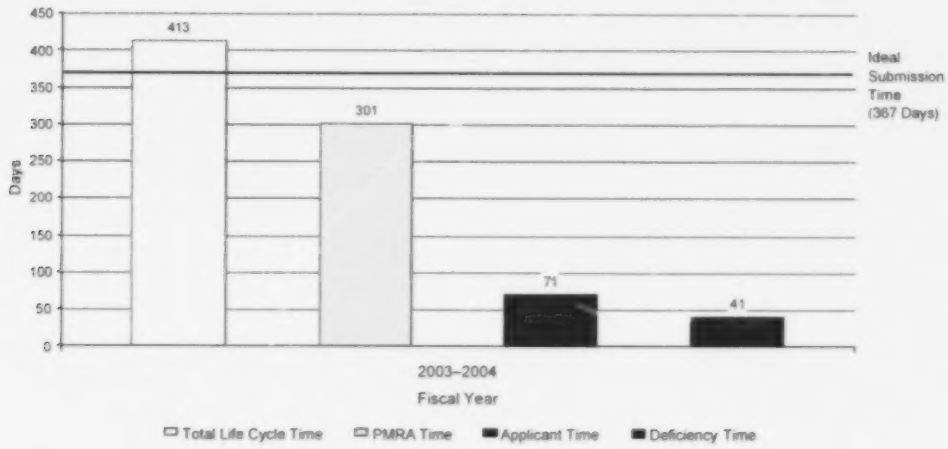


Chart 8 shows the actual times to registration for one reduced-risk submission for a microbial. The total time to registration was 413 days. The PMRA time of 301 days compares favourably with the expected ideal time of 367 days. The applicant needed 71 days to provide corrected or missing information, and the PMRA needed an additional 41 days (deficiency time) to examine this information.

Chart 8 Category B Reduced-Risk Microbial Submission Subject to the MOSP with Ideal Submission Time of 367 Days: Average Times to Registration (Including Deviations)

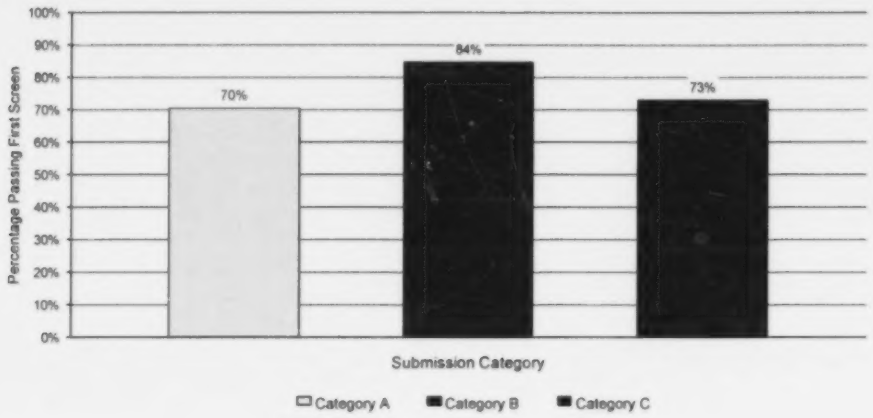


Applicant Performance

Applicants and the PMRA have been working to reduce the amount of applicant time and the resulting deficiency time. One of the measures used to measure performance is the percentage of submissions that pass screening on the first attempt. By passing the first screen, approximately 90 days (45 days of applicant time and 45 days of deficiency time) may be saved on the total time to registration.

Chart 9 indicates the performance on this indicator. Applicants improved their performance on Category A and B submissions; 70% and 84% of the submissions, respectively, passed the screening stage on the first attempt. Category C performance slipped slightly to 73%, compared to 76% in 2002–2003.

Chart 9 Percentage of Category A, B and C Submissions Passing First Screen (2003–2004)



Joint Review

The Joint Review Program, created by the NAFTA TWG, has been in existence since March 1996. Building on experience with increasingly more complex joint review submissions, Canada and the United States were able to launch a pilot project in November 2003 for the joint review of products for minor crops and uses. Through this initiative, the American and Canadian governments are directing resources to both the generation and review of residue, efficacy and crop tolerance data on growers' priorities. The PMRA and the USEPA are working closely with AAFC, the United States Department of Agriculture (USDA) IR-4 program and growers to encourage the joint submission of minor use products. Under the pilot, data are being generated for submission of fenhexamid on pome fruit and ginseng, S-metolachlor on winter squash and acetamiprid on greenhouse tomatoes.

A total of 51 registrations for active ingredients and end-use products have been granted under the Joint Review/Workshare programs, including one minor use label expansion and one import MRL. The registrations include 23 traditional chemicals, 20 reduced-risk chemicals, 4 microbials and 2 pheromones. Fourteen registrations for active ingredients and end-use products were completed in 2003–2004, with a total of 54 uses registered; see Appendix IV for details. Moreover, 11 submissions entered the Joint Review/Workshare programs during the same time period, of which 7 are traditional chemicals, 2 are reduced-risk products and 2 are microbials.

Joint Review Highlights 2003–2004

- The PMRA and the USEPA worked closely with registrants to prepare three fully electronic submissions for submission in March 2004 as potential joint reviews. These submissions tested the electronic index (e-index), a tool developed by the PMRA that supports the creation of a single electronic submission that can be submitted to several countries. Significant review efficiencies are expected as the study reports in these electronic submissions were also formatted according to NAFTA templates.
- The first jointly reviewed rodenticide, EXIT™ ISP, received simultaneous registrations in April 2003 from the PMRA and the USEPA. EXIT™ ISP is a reduced-risk product for control of ground squirrels.

- In October 2003, the PMRA and the USEPA registered boscalid (BAS 510) through the joint review initiative for reduced-risk chemicals. The product is registered as a foliar fungicide for beans, canola, lettuce, fruiting and bulb vegetables, potatoes, carrots, stone fruits, grapes and berries (in addition to a domestic turf use), representing 38 new uses.
- Clothianidin, an insecticide seed treatment, to control flea beetle on canola/rapeseed and corn rootworm, corn flea beetle, black cutworm, seed corn maggot, wireworm and white grub on corn was registered in December 2003 as a result of a joint review of a Group 2 non-reduced-risk chemical.

From 1 April 2003 to 31 March 2004, 10 joint review submissions completed and registered. New active ingredients, products and uses are listed in Appendix IV.

Fifty percent of the submissions met the applicable review performance standards in the United States and Canada. Of those submissions that did not meet the review performance standard, 3 submissions missed the standard by 28 days and two by 51 days.

Charts 10 to 13 show the total times to registration of the joint review submissions registered in 2003–2004. In all cases, the PMRA time was less than the expected ideal time for the submissions. The total times to registration vary from 820 days to 1367 days. This range is due to the different review performance standards (365 days to 845 days) and the resulting different ideal times (552 days to 1032 days). The applicant needed from 114 to 245 days to provide corrected or missing information, and the PMRA needed an additional 95 days to 251 days (deficiency time) to examine this information.

Chart 10 Priority Category A Submissions Subject to the MOSP with Ideal Submission Time of 552 Days: Average Times to Registration (Including Deviations)

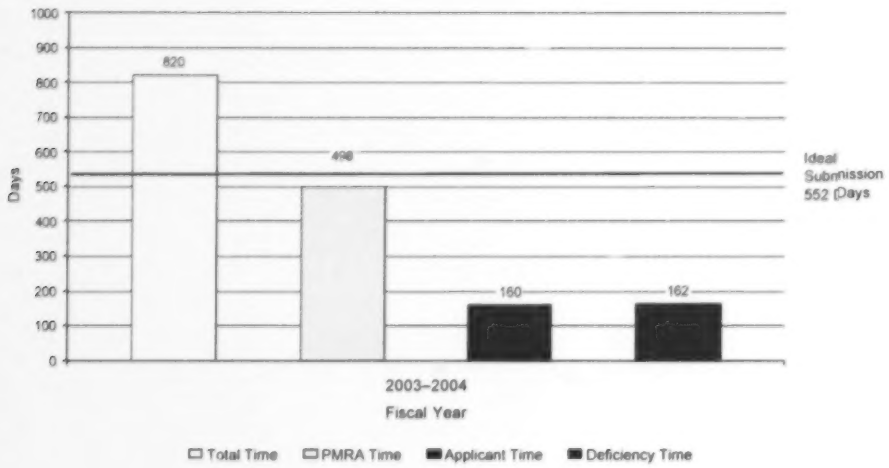


Chart 11 Three Priority Category A Joint Review Submissions with Ideal Time of 630 Days: Average Times to Registration

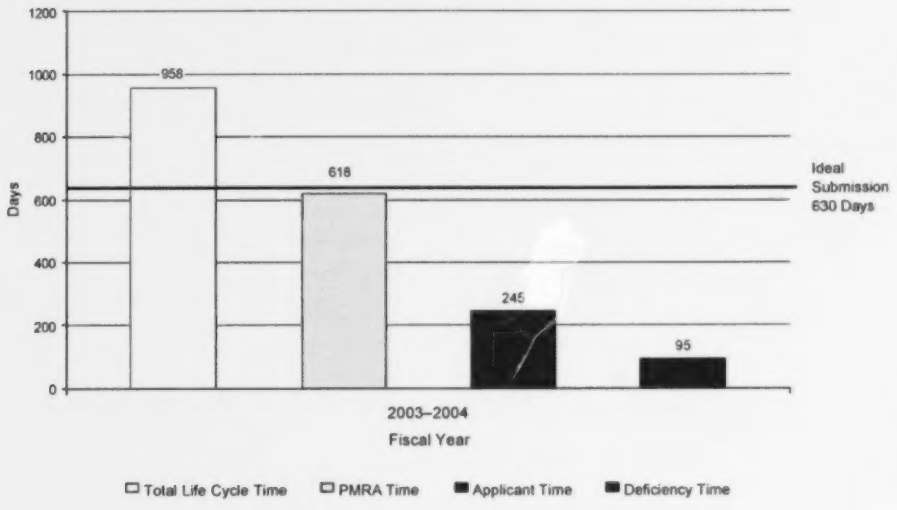


Chart 12 Three Category A Joint Review Submissions with Ideal Time of 737 Days: Average Times to Registration

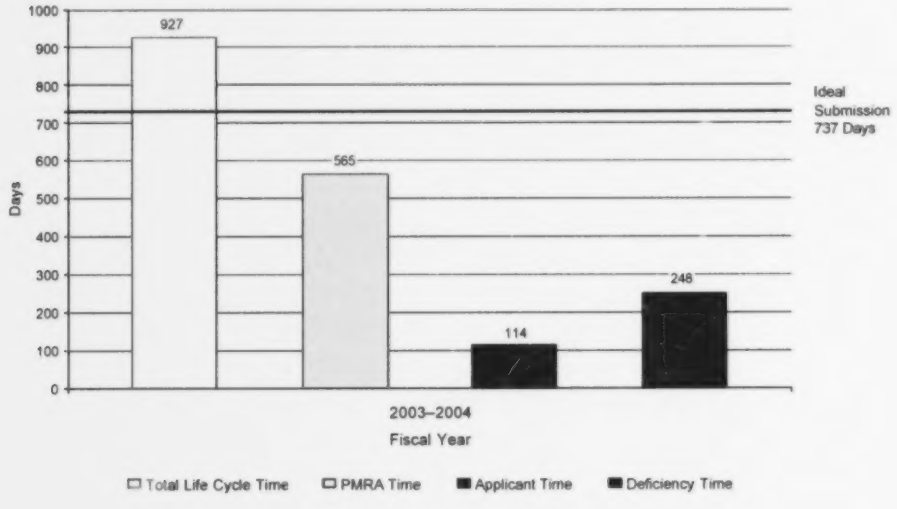
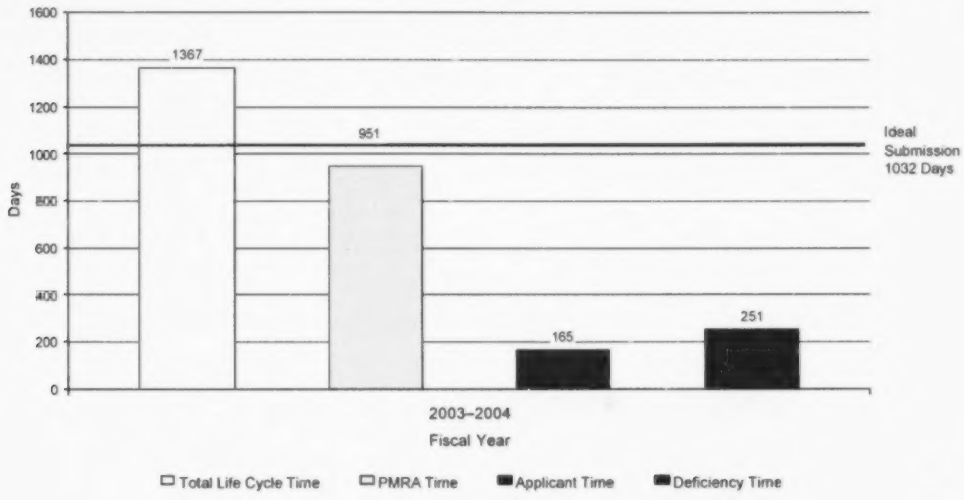


Chart 13 Two Priority Category A Joint Review Submissions with Ideal Time of 1032 Days: Average Times to Registration



Minor Use Initiative

Pesticide products for minor use needs are used in such small quantities that manufacturers find the sales potential insufficient to seek a registration in Canada. Therefore, such products may not be available domestically, although many are regarded as essential to cost-effective pest control and to the competitiveness and sustainability of agriculture, forestry, aquaculture and other sectors. Consequently, the PMRA has established dedicated user-sponsored programs for the registration of products for minor uses.

One of these programs is the User Requested Minor Use Label Expansion (URMULE) program. As published in Regulatory Directive DIR2001-01, *User Requested Minor Use Label Expansion*, the URMULE program considers adding new minor uses to the label of an end-use product, whether chemical, microbial or a pheromone, when both the active ingredient and the end-use product currently are registered in Canada. The use expansion is considered only if the product is efficacious and the risks are acceptable.

A total of 302 minor uses were registered in 2003–2004, 130 of which were reduced-risk uses. These registrations were the result of both user-sponsored URMULE submissions and registrant submissions for new active ingredients and major new uses. Appendix V provides further summary information. In addition, the Agency publishes regular updates of minor use registrations that can be found on the PMRA website.

In 2003–2004, the PMRA reviewed 132 AAFC and provincial/forestry URMULE presubmission consultation proposals, issued corresponding data requirements and reviewed 82 provincial submissions in support of minor use registrations. This included 31 of the 35 projects prioritized at the initial March 2003 Minor Use Pesticide Priority Setting Workshop, and 16 joint AAFC/IR-4 projects.

Key to the availability of products for minor uses is submissions for new active ingredients that allow for the approval of both major and minor uses. In addition to formal programs for minor use, the PMRA is also continuing to encourage registrants to participate in joint reviews, through which a registrant can obtain registration at the same time in Canada and the United States. This process usually leads to pesticide submissions that seek approval for numerous uses of the pesticide in Canada, many of which are for minor crops. (For information on joint reviews including the joint review of minor uses, please see the Joint

Review section.) The PMRA is also encouraging registrants who are seeking registration in Canada only to include as many uses as possible in their initial submission, including minor crops, and also to consider crop groups, thereby facilitating earlier availability of products to address minor use needs.

Reduced-risk Pesticides

A key initiative that facilitates the introduction of reduced-risk pesticides into Canada is the Joint Review Reduced-Risk Program (see the Joint Review section). Under this initiative, reduced-risk chemicals and biopesticides are jointly reviewed by the two countries and given reduced timelines or reviews.

The May 2002 PMRA Initiative for Reduced-Risk Pesticides was designed to facilitate Canadian access to reduced-risk products already registered in the United States. This program offers shorter review timelines for products that meet the USEPA criteria for reduced-risk chemicals or their biopesticide designation.

As of 31 March 2004, 72% of the chemical active ingredients and 31% of the biopesticide active ingredients designated as reduced risk in the United States were registered or pending registration in Canada. A total of six new reduced-risk chemicals and two new biopesticides were registered in Canada in 2003–2004. Appendix VI presents additional information new reduced-risk products.

Data requirements for the registration of microbials and pheromones have been established, recognizing the unique characteristics of these pesticides. Requirements for registration of pest control products containing pheromones and other semiochemicals are outlined in Regulatory Proposal PRO2002-02, *Guidelines for the Research and Registration of Pest Control Products Containing Pheromones and Other Semiochemicals*. The PMRA has received and reviewed stakeholder comments on these guidelines and is incorporating these comments in a Regulatory Directive. Further meetings with stakeholders during 2003 on registration of these types of pest control products provided additional material for a Regulatory Directive.

Research Permits

Between 1 April 2003 and 31 March 2004, the PMRA received 127 research permit and research notification applications. During this same period, the Agency issued 71 research permits and approved 24 research notifications.

Emergency Registrations

Regulatory Directive DIR2001-05, *Registration of Pesticides for Emergency Use*, describes the procedure for registering pesticides for emergency control of pest infestations.

In general, a request for emergency registration is initiated when the following situations occur:

- a pest outbreak or pest situation occurs that can cause significant economic, environmental or health problems;
- there is no effective product or application method registered in Canada for the control of the pest; and
- there is no effective alternative control method available.

Only new uses of currently registered products can be considered for registration because the active ingredients for those products have already been assessed. Under the emergency registration program, there is insufficient time available to conduct the full human and environmental health risk assessment needed for a previously unregistered product.

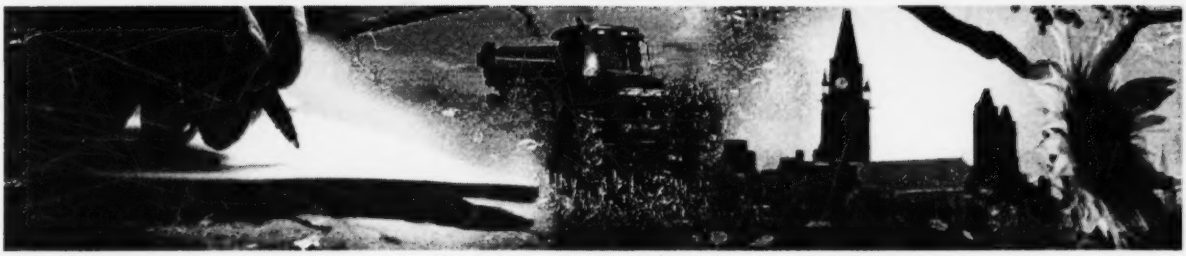
Between 1 April 2003 and 31 March 2004, the PMRA received 39 emergency requests. During the same time period, the Agency granted 25 emergency registrations. See Appendix VII for details.

Maximum Residue Limits for Food

When pesticides are used on crops grown for human or animal consumption, residues may remain in or on the food when it is sold. Before a pest control product can be registered for use in Canada, the PMRA must determine that consumption of the residues that are likely to remain in or on the food when the pesticide is used according to label directions will not pose an unacceptable health risk. This amount is then legally established as an MRL under the Regulations of the *Food and Drugs Act*.

Canadian MRLs apply to residues in or on food produced in Canada. To prevent residues in or on an imported food from posing an unacceptable health risk, MRLs are also established for pesticides not registered for use in Canada and for Canadian registered pesticides with respect to uses that are not authorized in Canada. If residues exceeding an MRL are found, the food is considered adulterated and is prohibited, under the *Food and Drugs Act*, from sale in Canada.

In 2003–2004, a total of 75 final MRLs were published in the *Canada Gazette*, Part II. A total of 76 proposed MRLs and 4 Interim Marketing Authorizations, covering 7 MRLs, were published in the *Canada Gazette*, Part I. As well, a corrective amendment was published in the *Canada Gazette*, Part II, which corrected an error in terminology. Appendix VIII lists the MRLs published during this time.



7.0 Re-evaluating Registered Products

Today, close to 550 pesticide active ingredients are in more than 7000 products that are registered under the PCPA for use in Canada. At the time of their registration, these pesticides were considered acceptable on the basis of an assessment of their safety, merit and value. However, the scientific knowledge that forms the underpinning of these assessments is continually evolving, and new methodologies and tools are being integrated into regulatory risk assessments. The re-evaluation of older pesticides takes into consideration the completeness of the data package, the full extent of the use patterns of the active ingredients, the diversity of their end-use products, and their market penetration. For these reasons, the PMRA has developed a re-evaluation program that uses current scientific approaches to examine the continued acceptability of older active ingredients and their end-use products. These modern approaches to risk assessment include applying additional safety factors to protect children, considering aggregate exposure from combined dietary, residential and drinking water exposure as well as taking into account the cumulative risk for chemicals considered to exhibit a common mechanism of toxicity. The PMRA's scientists have developed new methodologies and science policies to equip the Agency with the tools to conduct the most advanced and modern risk assessments possible.

The PMRA's re-evaluation program is described in Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*. The new approach to re-evaluation, recommended by stakeholders and supported by PMAC, is to build on available foreign reviews and expand the extensive worksharing arrangements with the USEPA. This internationally harmonized approach will increase regulatory efficiency and help to maintain a level Canada–United States playing field for trade in agricultural and other products treated with pesticides.

The PMRA has committed to re-evaluate all products registered on or before 31 December 1994. Of the 550 currently registered pesticide active ingredients and their end-use products on the market in Canada, 405 meet this criteria. This number has been reduced to 401 because 4 disinfectant active ingredients are no longer regulated under the PCPA. The strong reliance of the Canadian re-evaluation program on the availability of American reviews ties the completion of the Canadian program to that of the American program. The PMRA aims to complete re-evaluation of these older active ingredients within the same time frame as the USEPA: 2008–2009.

Status of Re-evaluation

The PMRA's workplan for April 2003 to June 2004 was published in November 2003. Successful completion of that workplan is marked by completion of the reviews for 40% of the active ingredients in the current re-evaluation program.

In fiscal year 2003–2004, 84 active ingredients were re-evaluated. The outcomes of these decisions are summarized in Table 3. Approximately 83% of the PMRA's decisions parallelled the USEPA's decisions. Details concerning the active ingredients involved in these decisions are available in Appendices IX.

Table 3 Summary of Proposed and Final Re-evaluation Decisions During Fiscal Year 2003–2004

	Published*		In Publication**	
Re-evaluation Decisions	**Final Decisions**	**Proposed Decisions**	**Proposed Decisions**	**Total Decisions**
Active ingredients	29	7	48	84
· Discontinued/withdrawn by registrant	23	—	—	23
· Phase-out requested (or proposed for phase-out) as a result of PMRA review	2	—	2	4
· Registration continued—label modifications	2	7	45	54
· Registration continued—no label modifications	2	—	1	3

* Re-evaluation decisions have been made, proposed to be made or registrants are discontinuing all products with that pesticide.

** Assessments have been completed and decisions proposed, but documents have not yet been published or companies have not yet been notified.

Highlights of re-evaluation activity 2003–2004

Some of the highlights of the re-evaluation program as of the end of 2003–2004 fiscal year are listed below.

- Reviews of the remaining insect repellants (two active ingredients) were completed and are in the publication process.
- The re-evaluations of the most common turf herbicides (a total of nine active ingredients) were completed and are in the publication process.
- An assessment of the impact on human health of the herbicide atrazine when used on corn was completed. The environmental assessment is expected to be completed in 2004–2005.
- The occupational risk assessments for four antisapstain chemicals have been completed and are in the publication process.
- The PMRA is actively cooperating with the USEPA in the re-evaluation of the three heavy duty wood preservatives (CCA, creosote and pentachlorophenol). Preliminary assessments for CCA and creosote have been published for public comment. Both agencies are considering the comments received.
- A modern safety assessment of malathion use in mosquito abatement programs was published, indicating this use continues to be acceptable.

- The re-evaluation of the organophosphate pesticides continues. Final decisions to phase out two organophosphate compounds (terbufos, azinphos-methyl) were published, and two active ingredients (tetrachlorvinphos and fenitrothion) were proposed for continuing registration with measures reflecting the modern risk assessment. Fenitrothion was subsequently withdrawn by the registrant after the consultation phase. The PMRA has now addressed a total of 20 organophosphate compounds.

Added to the accomplishments of previous years, a total of 143 active ingredients have now been addressed in the current re-evaluation program. Publications providing details of most of these pesticides are available on the PMRA website.

8.0 Promoting Sustainable Pest Management

Risk-reduction Strategies for Agricultural Pesticides

In May 2002, the ministers of Agriculture and Agri-Food Canada (AAFC) and Health Canada (HC) announced a joint initiative aimed at reducing pesticide risks and enhancing sustainable agriculture. Among other accomplishments, a MOU (described in the Federal Partners section in Chapter 3) was signed by the two Ministers. As outlined in the MOU, an AAFC-PMRA working group on risk reduction has been established and holds frequent meetings to gain consensus on approach, to develop workplans and to monitor progress in implementation.

Following consultations with several advisory groups, the PMRA and AAFC finalized a program framework for a voluntary, user-driven, commodity specific risk-reduction program for pest management in agriculture. The framework outlines a flexible process for developing and implementing the strategies, which may include the following steps:

1 Publication of a crop profile that outlines the status of the crop, including information on pests and tools to control them;

2 Publication of an issue document describing growers' needs for pest control for the commodity;

3 Organization of a stakeholder meeting to address needs (development of the strategy);

4 Finalization of and agreement to the strategy;

5 Implementation of the strategy;

6 Measurement of the performance of the strategy.

In addition, the PMRA completed a peer review of 10 crop profiles prepared through AAFC. A communications plan is being developed and the sustainable pest management webpage has been significantly revised. The Joint PMRA/AAFC Working Group on Risk Reduction organized a "Lessons Learned" Workshop and is integrating the knowledge gained from workshop into future work.

Completed Risk-Reduction Projects

Integrated Fruit Production

Initiated in 1998, Integrated Fruit Production (IFP) is a program led by the Canadian Horticultural Council with the involvement of the PMRA, AAFC and the World Wildlife Federation. The first edition of the *Integrated Fruit Production Guidelines for Apple Orchards in Canada*, approved by all four apple-producing regions, was published for the 2003 crop season. A measurement system—the Canadian Apple Growers National IPF Self-Assessment Evaluation—was developed as part of the Guidelines and was tested in 2002 by pilot-project participants. Further refinements were made based on grower feedback, and the self-assessment evaluation was published in the same booklet as the 2003 Guidelines. Each province/region has developed its own IFP protocols that meet the national IFP Guidelines. Nova Scotia, Quebec and Ontario have developed specific red–yellow–green lists of chemical products. Some provinces have developed a separate IFP guidebook (Quebec, British Columbia, Ontario), while others have adopted the national IFP guidelines (Nova Scotia, New Brunswick). Work progressed through the season on developing a method to measure IFP adoption in Canadian apple production and to establish a baseline and benchmarks, resulting in an written IFP adoption survey to be carried out in 2004. An IFP brochure was drafted to draw consumer support for the program as well.

Aquaculture Risk Reduction

The Aquaculture Risk Reduction project, concentrating on the control of sea lice, was completed in 2003 with the publication of two IPM documents: *Overview: Integrated Pest Management of Sea Lice in Salmon Aquaculture* and *Fact Sheet on Integrated Pest Management of Sea Lice in Salmon Aquaculture*. The project was undertaken by a National Working Group on the Integrated Management of Sea Lice and organized by the PMRA and the Salmon Health Consortium. The documents provide information that will assist the industry to manage the problem of sea lice in an effective, economic and environmentally sound manner over the long term.

Like many industries, pests are often present in aquaculture and can be the source of significant production and environmental problems. An example is sea lice, which can cause serious disease in farm-reared salmonids, leading to losses from direct mortality, poor growth, treatment costs and increased labour cost. The use of long-term pest management strategies for controlling sea lice is important to the sustainabilty of the industry and the environment in which it operates. By using a combination of prevention and treatment tactics, operators can achieve more consistent, long-term pest control.

Cranberry Integrated Pest Management

The Cranberry IPM Project resulted in the publication of the *Eastern Canada Cranberry IPM Manual*. This IPM manual, designed for eastern cranberry growers, complements a similar manual available to western cranberry growers. The process began in 1998, when growers, provincial officials, researchers and pesticide manufacturers recognized the need for sustainable production practices in cranberry production. Because both Canadian and American growers would benefit from this manual, this activity was recognized as a NAFTA project.

Ongoing Risk Reduction Projects

Canola

The PMRA has been collaborating with the Canola Council of Canada on the development of an on-line, decision-support system for canola growers, which will be implemented later in 2004. This collaboration is part of a risk-reduction project that was initiated in 1997 to develop a sustainable pest management strategy for this commodity. As a result of this risk-reduction project, which was later extended as a NAFTA project, several activities have served to promote IPM awareness among North American canola growers. A steering committee coordinated work, with the Canola Council of Canada and the PMRA serving as co-leads. The earlier publication of a number of extension documents in the context of this project has culminated in this on-line information system that will be hosted on the Canola Council of Canada website.

Pulses and Dry Beans

Growers of field peas, lentils and chickpeas (pulses) in Canada and the United States agreed to initiate a risk-reduction project in 2002. A work group consisting of American and Canadian growers, pest control advisors and university researchers along with representatives from the USDA, USEPA, AAFC and PMRA met for two days in Saskatoon, Saskatchewan, in June 2002.

The purpose of the meeting was to identify the needs of pulse growers in the two countries with reference to possible regulatory actions regarding pesticides. The meeting resulted in a list of critical needs, general conclusions and tables presenting the timing of operations and the efficacies of various management tools for specific pests. The resulting document and its appendices are intended to serve as a comprehensive foundation for pest management transition in pulse crops in the United States and Canada. The strategy is now being implemented.

Subsequently, concerns regarding trade barriers, continued reliance on specific pest control products and the lack of new tools have caused the dry bean industry to investigate these issues and identify the appropriate concrete actions. A bean-industry stakeholder meeting held in February 2003 led to the development of a strategy in June. The strategy includes a regional approach to the growers' main pest problems. The strategy also focuses on specific diseases (white mould, bacterial blight and early yellows) and alternatives for insect control (leafhoppers, seed corn maggot and tarnished plant bugs). Finally, the strategy addresses options available for weed control.

As a result of discussions among growers in the three NAFTA countries, a project with the involvement of growers and regulators in the three countries is now being undertaken to address the pest management issues being faced by the pulse industry. A description of this project can be found on the PMRA's website.

Integrated Pest Management for the Potato Industry in Prince Edward Island and New Brunswick

More than sixty people attended a two-day meeting in March 2003 to discuss sustainable potato production in Prince Edward Island and New Brunswick in March 2002. Attendees included conventional and organic potato growers from Prince Edward Island and New Brunswick, processors, several environmental groups, academics, pesticide industry representatives as well as government officials from these two provinces and from the federal government.

Drawing from the issues identified at the meeting, a Steering Committee involving growers, researchers, the pesticide industry, and federal and provincial officials developed a strategy to address a number of key issues to reduce pesticide risks. Through the strategy, actions will be taken to address land management issues and nutrient management, to improve access to new technologies including new reduced risk pesticides, strengthening of IPM, and to undertake research and improve the sharing of knowledge, as well as addressing issues regarding funding and incentives. Implementation of the strategy is underway; the PMRA is chairing the Steering Committee and providing secretariat services

Richardson's Ground Squirrel Control

The control of the Richardson's ground squirrel is a problem for ranchers and farmers as well as for people living in urban areas. A risk reduction project is being undertaken to identify sustainable ways to control this pest, including identifying reliable alternatives to strychnine, which is currently undergoing re-evaluation. A stakeholder steering committee was formed in June 2003 with representatives of growers, the pesticide industry, provincial officials, researchers, AAFC and the PMRA. This committee has developed a "pest profile", that is, a description of Richardson's ground squirrels, control methods and issues to be addressed. Subsequent meetings have identified resources available for determining knowledge gaps identified in the pest profile, and work is continuing on a management strategy. Ground squirrel control options—including research into economic effects of ground squirrels, development of action thresholds for toxicant use and exploration of non-chemical control options—were prioritized. The committee endorsed interim measures until a complete management strategy could be completed.

Forestry

The Forest Pest Management Caucus, in collaboration with the PMRA, has developed an IPM document on spruce budworm. The document will be published in 2004–2005.

Spruce budworm is a major cyclical defoliator of spruce and fir forests across Canada and in parts of the northern United States. Its impact varies in different regions and, given each jurisdiction has unique circumstances, management decisions and actions can be highly variable. The document outlines the principles, available methods, limitations and future needs of an IPM program for spruce budworm in Canada. Under the IPM program, these decisions are taken within a larger context of pest management, integration of non-timber forest resources and sustainable forest production.

Alternatives to Methyl Bromide in the Food Processing Sector

As a result of the Montreal Protocol, the food processing sector is faced with the phase out of methyl bromide by 1 January 2005. The PMRA has participated for a number of years in working groups with stakeholders and other federal departments to identify alternatives to methyl bromide.

In 2003–2004, the PMRA continued to collaborate on the Alternatives to Methyl Bromide Group and the EC advisory group. The food processing sector is exploring alternatives to methyl bromide, based on PMRA registration activities. Information on the PMRA's position on methyl bromide was conveyed in RRD2004-01, *Re-evaluation of Methyl Bromide*.

New Risk Reduction Projects

Tomatoes

During 2003–2004, the PMRA worked with Canadian tomato growers, as well as with colleagues in from the USEPA and the Comisión Intersectorial para el Control del Proceso y Uso de Plaguicidas, Fertilisantes y Sustancias Tóxicas (CICOPLAFEST), to determine interest in a NAFTA project on risk reduction and resolution of trade irritants for tomatoes. In March 2004, the PMRA met with grower organization representatives from Ontario and British Columbia to explore their needs for project participation.

Varroa Mites and Honey

In response to a need expressed from the beekeeping industry, the PMRA organized a teleconference with provincial specialists and FPT members. This meeting was held in February 2004 to discuss the problem of Varroa mites and to explore the potential for the development of a national IPM strategy for honey producers.

Pesticide Risk Indicators

A Federal/Provincial/Territorial Pesticide Risk Indicator Working Group was formed in 2003 to serve as an exchange forum on pesticide risk indicators. The Working Group strives to develop recommendations for a pesticide risk indicator that would be reliable, robust, and practical to use, and would express the overall risk for each pesticide active ingredient. It also provides recommendations concerning the adoption of a risk indicator model, adaptable by jurisdictions, that would ensure consistency between provinces in their use of pesticide risk indicators. The PMRA chairs the Working Group. Membership includes representatives designated by the PMRA and representatives for each provincial and territorial government, as designated by those jurisdictions.

During 2003–2004, the working group:

- developed terms of reference and a workplan;
- determined criteria that would assist in the selection of a pesticide risk indicator;
- assessed existing risk indicators for their consistency with the criteria;
- undertook a survey of FPT members to obtain information regarding their experience with pesticide risk indicators and their need for such an indicator; and
- organized a very successful workshop that was attended by representatives of most jurisdictions.

In addition, AAFC representatives were invited to participate and to present information regarding their experience with pesticide risk indicators. Workshop participants validated the criteria for indicator choice that the working group had developed and provided advice to the working group on the way forward.

Resistance Management

Under the auspices of NAFTA, Canada and the United States have joined together to develop and publish guidelines for voluntary pesticide resistance-management labelling for implementation in North America. As part of this initiative, the PMRA published Regulatory Directive DIR99-06, *Voluntary Pesticide Resistance-Management Labelling Based on Target Site/Mode of Action*.

Ongoing since 1999, this voluntary labelling initiative provides resistance management information on agricultural products labels. As a result, 507 pest control products now display mode of action group and resistance-management statements on their label.

Sustainable Development Strategy

One of the key tools used by the federal government to advance sustainable development is the preparation and implementation of Sustainable Development Strategies (SDSs). Health Canada has tabled three SDSs in Parliament to date: one in 1997, another in 2000 and the most recent, Becoming the Change We Wish to See, in March 2004.

The PMRA's contribution to the success of these strategies has been through meeting all of its stated outcomes in the 1997 and 2000 strategies. The second Sustainable Development Strategy, *Sustaining Our Health*, focussed on the Department's commitments to take account of the environmental, social/cultural and economic factors that influence health and well-being. These commitments were organized around three priority themes:

Theme 1 Helping to create healthy social and physical environments;

Theme 2 Integrating sustainable development into Departmental decision-making and management processes;

Theme 3 Minimizing the environmental and health effects of the Department's physical operations and activities.

The PMRA contributed to all three themes. For example, one of the PMRA's targets was to reduce the risks to children's health from selected products and environmental hazards and to promote healthy environments for children. The PMRA completed this target by publishing and implementing Science Policy Note SPN2001-01, *Guidance for Identifying Pesticides that have a Common Mechanism of Toxicity for Human Health Risk Assessment*. This Science Policy Note describes the approach that PMRA uses to identify pesticides that cause common toxic effects by common mechanisms of toxicity. The cumulative risk assessment process is one of three key child-specific considerations used by the Agency in assessing risks to children's health from exposure to pesticides.

The PMRA will continue its support of sustainable development principles in the 2004 strategy by improving its process for making regulatory decisions for pest control products, including providing access to safer products. The Agency will provide information on pest control products and on sustainable pest management practices. More details about current and previous sustainable development strategies are available on Health Canada's website.

Sustainable Urban Pest Management

In October 2000, the Minister of Health announced an Action Plan for Urban Use Pesticides developed through a partnership between the PMRA and provincial and territorial governments. The Action Plan was one of the first steps that the government took as part of its response to the Standing Committee on the Environment and Sustainable Development's report, *Pesticides: Making the Right Choice for the Protection of Health and the Environment.*

This action plan contains three elements: a Healthy Lawns Strategy that encourages reduced reliance on lawn pesticides; encouraging the development and registration of reduced-risk pesticides as quickly as

possible; and the re-evaluation of the eight major pesticides used in lawn care against stringent standards adopted in Canada and the United States.

In 2003–2004, the following accomplishments resulted from this collaborative effort.

- A homeowners' survey was completed in which 188 people participated. The survey aimed to gauge the success of training materials and programs in educating homeowners on healthy lawn practices that minimize the need for pesticides. Results and analysis are posted on the Healthy Lawns website.
- Over 32 000 copies of the *Healthy Lawn Tips* folder were distributed to individual homeowners as well as to municipalities, provinces and regional and federal organizations for distribution to the public.
- A poster entitled "Read the Label" was developed to remind consumers to read pesticide product labels.
- A training module for lawncare and landscape service providers was finalized through participation on the FPT Working Group on Pesticide Education, Training and Certification. The Landscape Module incorporates IPM concepts to reduce reliance on pesticides in lawn care, such as preventing pests, using reduced-risk products and applying pesticides only when necessary.

Integrated Pest Management in Federal Custodial Operations

In its October 2000 response to the Report of the House of Commons Standing Committee on the Environment and Sustainable Development, the government committed to review its current activities, policies and directives concerning pesticide use in the light of the Standing Committee recommendations and in keeping with its approach to pesticide risk reduction and use reduction within the context of sustainable pest management. The review will include determining the extent of pesticide use and of adoption of pest management plans.

To these ends, an interdepartmental working group has been established. The working group has drafted a best practices document on the use of lawn care pesticides in federal custodial operations. The document is now being reviewed by the Sustainable Development in Government Operations Environmental Management Systems Task Group, which reports to the Sustainable Federal House in Order Directors General Coordinating Committee. Ongoing work will focus on publication of the document, and quantifying the extent of pesticide use and departmental adoption of pest management plans.

Pesticide Education, Training and Certification

The FPT Working Group on Pesticide Education, Training and Certification was co-chaired by the PMRA and Alberta Environment in 2003–2004. The working group standardizes pesticide applicator and vendor certification as well as training programs across Canada, as the first line of risk mitigation within the overall goal of protecting human health and the environment. To that end, the working group is updating the basic knowledge requirements for pesticide applicators and vendors. In February 2004, the landscape module was updated with endorsement from the Canadian Nursery and Landscape Association. This module will serve as the basis for ensuring lawn and landscape service providers are trained and operate in a competent and professional manner. The landscape module as well as additional information on pesticide education, training and certification in Canada can be found on the PMRA website.

9.0 Compliance

In 2003–2004, the PMRA began developing a strategic plan to outline future directions and priorities for the compliance and enforcement program in light of the commitments made in response to the 2003 Report of the Commissioner of the Environment and Sustainable Development as well as the planned implementation of the new PCPA. Additional information on the Commissioner's report appears in Chapter 10, Continuous Improvement.

The Agency also developed and carried out the annual National Pesticides Compliance Program (NPCP), which is based on national and regional compliance issues.

Investigations and Enforcement

During 2003–2004, the Agency initiated more than 560 investigations of incidents of known or suspected violations of the PCPA and Regulations. In addition, the PMRA took more than 733 enforcement response actions on investigations initiated in this and previous years. The responses ranged from compliance education (written and oral) to product detention to Administrative Monetary Penalties (AMPs), which include fines and warnings. No prosecutions were initiated or completed. The following types of violations were detected[1]:

- 341 violations involving sale;
- 92 involving use;
- 23 involving manufacture;
- 42 involving labelling;
- 101 involving advertising; and
- 52 involving violation with respect to importation.

As one example of an investigation, the Atlantic Region investigated potential advertising and promotion violations raised by Earth Action in a petition to the Auditor General of Canada. Corrective action was achieved through education and verified through surveillance inspections. The outcome was communicated to Earth Action and the office of the Auditor General.

In 2003–2004, the third year of implementation of Administrative Monetary Penalties (AMPs) for PCPA offences, 17 AMPs were initiated, and 18 Notices Of Violation (NOVs) were issued, some of which were

1 Some cases resulted in more than one violation being identified; enforcement response delivered.

initiated in the previous fiscal year. Of the 18 NOVs issued, 11 were related to violations in the use of pesticides; 3 were for advertising violations, 3 were related to sale and 1was related to import. A list of the NOVs is found in Appendix X.

In four cases, the NOVs were challenged. As of 31 March 2004, one case is waiting for Tribunal hearing, one case is currently with Federal Court after receiving Minister and Tribunal Reviews, and in two cases, the Minister's Review overturned the issued penalties.

Compliance Promotion

During 2003–2004, the PMRA delivered one planned consultation program, Copper Sulphate Information Program, to educate, facilitate and promote compliance as well as communicate regulatory information. Compliance promotion includes a diverse range of activities such as compliance education, compliance outreach programs and the support of industry stewardship programs.

PMRA regional staff attend and participate in a number of meetings that contribute to compliance promotion. The following are a few examples.

- In the Quebec region, there were eight presentations to the pesticide industry and to provincial officials related to the recommendation of products where lower-than-label rates were being used and registration standards. Discussions were conducted to address a misuse problem, resulting in an agreement to coordinate follow-up inspections for 2004–2005.
- Manitoba officers made compliance promotion presentations to the Manitoba Weed Supervisors' Association, the Industrial Vegetation Management Association and the Manitoba Golf Course Superintendent's Association. PMRA regional staff participate on the Board of Manitoba's Plant Care Council, which is working on responsible pest control care and conservation. Regional staff also work with a number of commodity associations, such as the Manitoba Aerial Applicators Association, the National Sunflower Growers Association and Pulse Canada/National Edible Bean Growers.
- The Saskatchewan region provided updates on compliance programs and activities and outcomes to provincial and industry representatives on weeds and insect experts. This activity provided pertinent information to help ensure that accurate and up-to-date compliance information is provided to other important parties who indirectly contribute to compliance goals and objectives. In addition, regional officers sometimes obtain information that helps to develop regional compliance programs and to characterize the nature and extent of compliance problems.
- The Alberta region made two presentations to groups of certified applicators that provided credit for them in renewing/maintaining their applicator's licenses. These groups were the Alberta Aerial Applicator's Association and the Alberta Pest Control Association. PMRA regional officers attended meetings of the Prairie Pesticide Minor Use Consortium, where the industry groups that pool their money to support minor use research discuss their issues/priorities.
- Regional officers in British Columbia delivered a compliance promotion presentation to the Structural Pest Management Association, the Interior Environmental Pest Management Association, and the British Columbia Log Builders and Timber Framers Association.

Inspection for Compliance

The PMRA's consultation, inspection and investigation programs facilitate, encourage and maximize compliance with the PCPA and its conditions of registration, thereby helping to protect the health of Canadians and their environment.

In 2003–2004, two surveillance programs were carried out to target specific individuals or groups for follow-up verification of compliance based on previous findings or concerns. These programs included a general surveillance program and surveillance of pesticide use in greenhouse pepper production.

Eleven monitoring/inspection programs were undertaken to verify compliance of users, distributors and registrants of pest control products against specific terms and conditions of registration and/or the general provisions of the PCPA and Regulations.

- Registrant monitoring consisted of monitoring of research permits, registrant inspection, follow-up with registrants regarding the phase-out of non-agricultural uses of diazinon, verification of pepper spray products as a condition of registration, inspection of record-keeping regarding strychnine sales and guarantee analysis of pest control products.
- User monitoring programs consisted of a general program concerning pesticide misuse, a program regarding pesticide use on Asian vegetables and monitoring of compliance with antisapstain product labels.

Thirty-five program reports were finalized at the completion of the programs. As a result of the PMRA's 2003–2004 monitoring and surveillance activities, more than 1100 inspections were conducted.

Laboratory Program

Five hundred and two samples were submitted to the PMRA Laboratory, resulting in over 850 analyses in support of compliance activities. Of these samples, 77 were investigative, while 425 were inspection samples. The PMRA Laboratory analyses required the development of 8 new analytical methods and 16 analytical method validations.

In order for the Laboratory to maintain its ISO 17025 accreditation status, the following significant activities were carried out during 2003–2004:

- hosting of representatives of the Standards Council of Canada in March 2003, who conducted an audit to verify the level of conformity of the PMRA's quality assurance procedures to the ISO 17025 standards; and
- participation in three performance verification check sample programs (Laboratory Accreditation Program for Pesticide Residues, Southern States Check Sample Program, and the Association of American Pesticide Control Officials)—the Laboratory's results were deemed satisfactory, supporting the performance of the quality assurance system.

The Laboratory maintained its ISO 17025 accreditation for the 10th consecutive year, thereby establishing itself as a distinguished part of the Agency in terms of analytical expertise and integrity of results.

The PMRA collaborated with other government departments on a number of programs, including in the delivery of the "CFIA Guarantee Verification of Fertilizers Products containing Pesticides" program (157 samples for a total of 304 analyses). The Laboratory also provided analytical services (58 analyses) for a research project led by Environment Canada, the results of which will be published in scientific journals.

10.0 Continuous Improvement

Document Exchange/Dissemination: Upgrading the PMRA Workbook

The electronic workbook is a critical component of the PMRA's submission tracking system. It provides an integrated electronic document management system, serving as the repository for submission-related information (e.g., scientific studies, PMRA study evaluations, product labels and submission correspondence). The workbook also secures the foundation for electronic regulatory initiatives and enables seamless integration to a secure Internet portal for electronic transactions between the PMRA and registrants. It will also enable the PMRA to fulfil the transparency requirements of the new PCPA in an efficient manner.

During 2003–2004, the Workbook was redesigned to significantly improve its ease of use and functionality. The new version of the Workbook provides quick access for PMRA staff to approved templates for carrying out reviews. When a review is completed, the reviewer can, at the click of a mouse, safely archive the review. At the same time, the review is linked with related submission documents, and metadata about the review is created. In addition, all data submitted by registrants is now available in electronic form to registrants, as a result of a new, high-speed microfilm machine that converts paper data to an electronic format.

When fully implemented, this process will greatly increase efficiency: initial processing for record keeping, internal use and archiving of registrant data that would have taken a month or more in the past will be accomplished in a matter of a few hours. Paper use will also be significantly reduced. Recently, the PMRA received a submission on a single DVD weighing only grams; the same submission in paper form would have weighed over 500 kg.

The Workbook, only in its second year of life, now stores over 100 000 documents, including WordPerfect, PDF and Excel files. The Workbook allows PMRA staff to search the ever growing document repository with significant power. This system enhances the security of documents and facilitates a team approach to work.

Electronic Submissions

In 2003–2004, the PMRA began to update the Agency's electronic submissions program through work with industry and the USEPA to pilot innovative approaches for assembling, receiving, processing and reviewing of electronic submissions. As a result, PMRA received three paperless submissions in Spring 2004. Industry assembled these submissions using the e-index, a new tool developed and supplied by the PMRA. Endorsed by the NAFTA TWG, the e-index provided substantial efficiencies in the loading of the submissions into

the PMRA Workbook and reduced submission assembly software costs for industry. Industry also benefited substantially from not having to submit paper copies of their submissions, through reduced paper costs.

PMRA Electronic Regulatory Systems

In May 2003, the PMRA began the development of the PMRA Electronic Regulatory System (e-PRS), an on-line business portal through which applicants and registrants can conduct regulatory transactions with the Agency. PRS will be launched in September 2004; however, there were several key milestones achieved during 2003–2004:

- Integration with the Government's Secure Channel project, so that confidential business information can be exchanged between the PMRA and applicants/registrants in a secure fashion.
- Re-engineering of a number of PMRA's current electronic forms and the development of a consolidated on-line structured form.
- Integration of the e-PRS with PMRA's internal database and submission document management tool, the Workbook, so that data can be exchanged between external stakeholders and PMRA's internal systems.

Pest Management Information Service

The Pest Management Information Service (PMIS) is a single-window, 1-800 information service through which registrants, provinces, territories, stakeholders and the general public can make inquiries on several levels including pesticide regulations, registration procedures and policies, information on registered pesticides and issues related to the use of pesticides.

During 2003–2004, the PMIS responded to 9799 calls. Registrants accounted for 3637 of these calls, and individuals made a further 4296 calls. The remaining calls originated with governments, media, professionals, commercial and special interests as well as PMRA staff.

As part of its commitment to improving services, the PMIS administered a second user survey in the fall of 2003 as a follow-up to the 2002 survey. As recommended by the Treasury Board, both surveys used the Common Measurement Tool approach.

Changes already made, based on the initial survey, are as follows:

- the telephone menu has been improved, with several new features added;
- a direct link to the PMRA website from Health Canada's main page has been created; and
- the PMRA website has been made more user-friendly and provides users with updates on service improvements.

The second survey results confirmed that users continue to be very satisfied with the PMIS. Based on these results, suggestions for improvement will be studied, and plans for improvement will be implemented at a later date.

Report of the Commissioner of the Environment and Sustainable Development

The Commissioner of the Environment and Sustainable Development (CESD) is a specialized unit within the Office of the Auditor General of Canada that focusses on environmental and sustainable development issues. The CESD conducts environmental audits of the government's activities. Each year, the Commissioner reports on environmental and sustainable development matters that she believes should be brought to the attention of the House of Commons. In the 2003 *Report of the Commissioner of the Environment and Sustainable Development to the House of Commons*, Chapter 1, *Managing the Safety and Accessibility of Pesticides*, looked at the federal government's management of pesticides.

Of the Commissioner's nine recommendations in the Chapter, six were directed solely at the PMRA; the remainder were shared with other government departments. The recommendations involved strengthening pesticide evaluation, re-evaluating older pesticides more quickly, measuring the effectiveness of compliance activities, improving information to support regulatory decisions, coordinating research and monitoring as well as managing human resources.

In response, the PMRA has made a commitment to meet these recommendations. As outlined below, action on a number of items has been completed, while some will take a longer time to complete.

Continuing to strengthen pesticide evaluation	Action is ongoing.
Re-evaluating older pesticides more quickly	The PMRA published Re-evaluation Note REV2003-08, *PMRA Re-evaluation Program Workplan (April 2003–June 2004)*, on 18 November 2003. A document describing the process for determining how quickly pesticides should be removed from the market and for advising current users when older pesticides are found to have unacceptable risks is being developed. A final document will be published in fiscal year 2004–2005. As of 31 March 2004, the PMRA re-evaluation program has addressed more than 140 older pesticides by collaborating with the USEPA and sharing re-evaluation data. This is more than 35% of the active ingredients to be re-evaluated.
Measuring the effectiveness of compliance activities	Work is underway with provinces and territories, and with Canadian and international organizations with compliance mandates to determine how user compliance can be measured with limited resources.
Improving information to support regulatory decisions	Priority has been given to developing regulations for sales information reporting and adverse effects reporting under the new *Pest Control Products Act* . The proposed sales reporting regulation was published in the *Canada Gazette*, Part I, on 27 March 2004. The remaining regulations will be published in the *Canada Gazette*, Part I, as soon as possible.

Coordinated research and monitoring	Terms of Reference for the Interdepartmental Working Group on Pesticides have been revised. The first session to develop joint priorities for research and monitoring took place in December 2003. Ranking of risks to aquatic environments from pesticides and related work is underway.
Human resources management	Actions are complete.

Continuous Learning Program

The PMRA Continuous Learning Program is responsible for the management, development and coordination of operational, scientific and professional learning and development for staff; staff orientation; staff and management development programs; and internal communication, and learning activities, as well as learning for stakeholders including the pesticide industry, and provincial and territorial government officials.

Staff learning at the PMRA was higher than average during 2003–2004, with an average of 8.3 training days per employee. This number is mainly as a result of the influx of new staff and the introduction of a new development program for biologists and chemists. In general, 40% of the learning activities are directed to core competencies and 60% to operational, scientific and professional competencies. Core competencies include orientation, communication skills, information technology, interpersonal skills, office/business skills and management skills. Operational, scientific and professional learning includes in-house courses, field tours, conferences, seminars, information sessions as well as external training.

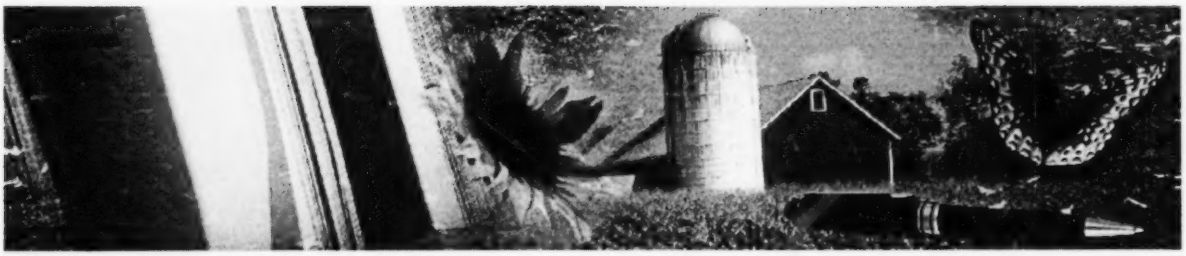
Some examples of the types of learning conducted in the last fiscal year are as follows:

- PMRA orientation modules for new PMRA staff;
- scientific writing course;
- learning on the new *Pest Control Products Act* and associated policies;
- a course on Pest Management and Pesticides on Turfgrass;
- a course on Reproductive/Development Endrocrine Toxicology;
- several field tours to provide learning on pesticide application practices and use patterns, including a minor use tour in Quebec, and tours focussing on antimicrobial pesticides (e.g,. a water treatment plant and pulp and paper industry tour); and
- multiple seminars, such as "Delineating Critical Habitat under the new *Species at Risk Act*".

Learning events were also held for PMRA stakeholders including a technical session on the new PCPA for provincial pesticide colleagues. Planning was initiated for industry training sessions on the new PCPA and "doing business electronically".

One recent key initiative was the implementation of a science-based development program for biologists and chemists. A first in the Public Service, the program provides a learning environment that leads to career advancement for the participants in a planned and consistent manner. It is based on competencies for the different job levels, and promotions are based on individual merit, without competition, as the program participants meet the required competencies for the next level. In 2003–2004, 133 biologists and chemists participated in the program, which resulted in 26 promotions after the first assessment cycle.

Another key accomplishment was the finalization of a Human Resource Strategy that formalized the integration of human resource planning into the strategic business plan and Agency planning process.



11.0 Resources

The PMRA is funded by public funds (i.e., appropriations) and external fees resulting from cost recovery regulations. Public funds represent approximately 85% of the Agency's resource base. Revenues from cost recovery make up the other 15%. The proportion of public funds has increased from 70% in 1998–1999 to 85% in 2003–2004. This is due to government funding of new activities and a decrease of $600 000 in external revenues. The tables below provide a summary of expenditures by business line and revenue by source.

Table 4 **Resources Allocated by Business Line**

Resource Summary 2003–2004

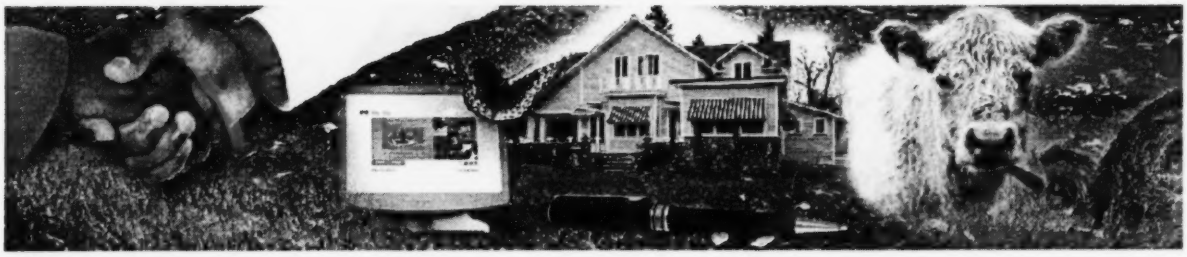
Expenditures	FTEs		$M	
BL1—New Product Evaluation	261	53%	22.8	49%
BL2—Registered Product Evaluation	111	23%	10.4	23%
BL3—Compliance	81	16%	7.1	15%
BL4—Sustainable Pest Management	23	5%	2.2	5%
BL5—Business Line Improvements	15	3%	3.7	8%
Totals	**491**	**100%**	**46.2**	**100%**

Table 5 **Agency Revenues by Source**

Revenues 2003–2004 ($M)*

Application Fees	3.1
Maintenance Fees	4.3
Totals	**7.4**

* The Agency charges a one time application fee for the review of an application to register a pest control product and an annual maintenance fee per registered product for the right to manufacture or sell a product in Canada.



12.0 Communicating with Our Stakeholders

The PMRA is committed to an open, transparent and participatory process for pesticide regulation. The Agency seeks the advice of its advisory bodies, works closely with its provincial/territorial partners, and solicits public comment on new policies and programs, on major pesticide registration decisions and on re-evaluation decisions. Information on the PMRA's extensive involvement in international pesticide-related efforts, notably the NAFTA TWG and the OECD's Pesticide Program, is circulated broadly and regularly. In addition, a consultation meeting with stakeholders is held prior to the yearly full meeting of the NAFTA TWG that involves stakeholder participation.

In 2003–2004, the Agency published 67 regulatory and other documents. Appendix XI contains a list of these publications.

The PMRA's website at www.pmra-arla.gc.ca contains all current PMRA publications including a wide range of information for industry and the general public. A notification service that provides a message when a new document is placed on the web is available on the site. PMRA Publications can be reached at pmra_publications@hc-sc.gc.ca.

As discussed in the earlier section on the Pest Management Information Service, the PMIS provides information on pesticide regulation and registered pesticides. All pesticide inquiries should be made to this service.

Pest Management Information Service-Pest Management Regulatory Agency

2720 Riverside Drive

Ottawa, Ontario K1A 0K9

Telephone: 1 800 267-6315 or (613) 736-3799

Fax: (613)736-3798

E-mail: pmra_infoserv@pmra-arla.hc-sc.gc.ca

List of Abbreviations

AAFC	Agriculture and Agri-Food Canada
AMC	Agency Management Committee
AMP	administrative monetary penalty
AMPs Act	*Agriculture and Agri-Food Administrative Monetary Penalties Act*
CCA	chromated copper arsenate
CFIA	Canadian Food Inspection Agency
EDDE	Electronic Dossier, Delivery and Evaluation
EMAC	Economic Management Advisory Committee
FTE	Full-time Equivalent
FPT Committee	Federal/Provincial/Territorial Committee on Pesticides and Pest Management
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
IBCA	invertebrate as a biological control agent
IFP	Integrated Fruit Management for a Sustainable Production
ILSI	International Life Sciences Institute
IPM	Integrated Pest Management
IR-4	United States Department of Agriculture's Interregional Research Project Number 4
MOSP	*Management of Submissions Policy*
MRL	maximum residue limit
NAFTA	North American Free Trade Agreement
NAFTA TWG	North American Free Trade Agreement Technical Working Group on Pesticides
NOV	Notice of Violation
NPCP	National Pesticides Compliance Program
OECD WGP	Organisation for Economic Co-operation and Development Working Group on Pesticides
OMAF	Ontario Ministry of Agriculture and Food
PCPA	*Pest Control Products Act*
PDF	portable document format
PIC	Prior Informed Consent
PMAC	Pest Management Advisory Council
PMRA	Pest Management Regulatory Agency

SAB	Science Advisory Board
SDS	Sustainable Development Strategy
URMULE	User Requested Minor Use Label Expansion
URMUR	User Requested Minor Use Registration
USEPA	United States Environmental Protection Agency
USPA	United States Department of Agriculture
WHMIS	Workplace Hazardous Materials Information System

Appendix I Submission Categories

Category A submissions include new active ingredients and their companion end-use product(s) as well as major new uses, or submissions to establish an MRL for a new active ingredient. User Requested Minor Use Registrations (URMURs) and joint reviews are also included in this category.

Category B submissions include submissions for new uses or new formulations.

Category C submissions are submissions that are based on previously established precedents or that have reduced data requirements.

Category D includes submissions to register or to amend products within particular programs, for example, Import for Manufacture and Export Program, Own Use Import, Master Copy, Private Label, User Requested Minor Use Label Expansion (URMULE) and renewals.

Category E includes submissions for research permits and research notifications concerning research carried out in Canada.

Appendix II Summary of PMRA Registration Actions for New Active Ingredients in Canada

(1 April 2003 to 31 March 2004)

New Active Ingredients Registered*	Totals	Temporary Registrations**	New Active Ingredients of Agricultural Interest
Total New Active Ingredients	18 (5)	15 (5)	13 (5)
Conventional chemicals	9 (2)	8 (2)	7 (2)
Total reduced-risk active ingredients	8 (3)	7 (3)	6 (3)
Conventional reduced risk chemicals	6 (3)	6 (3)	6 (3)
Biopesticides	2	1	0
Antimicrobials	1	0	0

Notes:

* Numbers in parenthesis ( ) represent registrations through joint reviews or workshare submissions with the United States Environmental Protection Agency.

** While the 2003–2004 proportion of registrations that are temporary is high, only 3% of total pesticide registrations are temporary; 97% of the total registrations are full registrations. Temporary registrations are granted when the risks are considered acceptable, that is when the product meets current health and environmental safety standards and is efficacious, but when only confirmatory or conditional data are required. Temporary registrations are issued by pesticide regulators in the same way in the United States and in Europe.

Appendix III New Active Ingredients Registered
(1 April 2003 to 31 March 2004)

Active Ingredient (CAS #)	Technical Product	End-use Product(s)
4,5-dichloro-2-octyl-3(2*H*)isothiazolone (64359-81-5)	Kathon 287 Technical Microbicide	Rozone 2000 Industrial Microbicide
Prallethrin (23031-36-9)	ETOC Technical Grade	ETOC Pressurized Spray 2594
Mecoprop-P (16484-77-8)	Mecoprop-P Technical Acid	
	Marks Mecoprop-P Technical Acid	
Dried Blood*	Plantskydd Dried Blood Technical Active Ingrediant Grade	Plantskydd Deer Repellent Soluble Powder Concentrate Plantskydd Deer Repellent Pre-mixed Rtu Solution
Famoxadone (131807-57-3)**	Famoxadone technical	Tanos 50DF Fungicide
Iodosulfuron-methyl-sodium (144550-36-7)	Iodosulfuron-methyl-sodium Technical Herbicide	Tribute Solo 32 DF Herbicide
Foramsulfuron (173159-57-4)***	Foramsulfuron Technical Herbicide	Option 2.25 SC Herbicide Option 35 DF Herbicide Tribute Solo 32 DF Herbicide
Fluazinam (79622-59-6)†	Technical Fluazinam Fungicide	Allegro 500F Agricultural Fungicide
Trifloxystrobin (141517-21-7)†	Trifloxystrobin Technical Fungicide	Stratego 250EC Fungicide Compass 50EG Fungicide Flint 50WG Fungicide
Fenamidone (161326-34-7)†	Fenamidone Technical	Reason 500SC Fungicide
(Bas 510) Boscalid (188425-85-6)** †	BAS 510 F Technical Fungicide	Lance WDG Fungicide Cadence WDG Fungicide
Imiprothrin (72963-72-5)	Imiprothrin Technical Grade	Multicide Pressurized Roach Spray 27341
Clothianidin (210880-92-5)**	Clothianidin Technical Insecticide	Poncho 600 Seed Treatment Insecticide Poncho 600 FS Seed Treatment Insecticide Prosper FL Insecticide and Fungicide Seed Treatment
Corn gluten meal (66071-96-3)*	Prairie Gold 60% Corn Gluten Meal	Turfmaize Preemergent Weed Seed Germination Inhibitor
Sodium α-olefin sulfonate (68439-57-6)** †	Exit™ ISP	Exit ™Concentrate Rodenticide
Brassica hirta white mustard seed powder** †		
Ethyloleate (111-62-6)	Hasten Spray Adjuvant	Hasten Spray Adjuvant
Methyloleate (112-62-9)		

* Reduced-risk biopesticide
** Joint Review
*** Workshare
† Reduced-risk chemical

Shaded products are intended for agricultural use

Appendix IV New Active Ingredients, Products and Uses Registered Through the Joint Review Process

(1 April 2003 to 31 March 2004)

Active Ingredient	Product Names	Uses	Date Registered
Clothianidin (TI435)	Clothianidin Technical	Insecticide for corn and canola seed treatment (5 uses)	May 2003
	Clothianidin 600TM		
	Clothianidin 600FS		
Boscalid (BAS 510)	BAS 510F Technical	Foliar fungicide for beans, canola, lettuce, fruiting and bulb vegetables, potato, carrots, stone fruit, strawberries, grapes, turf and berries (46 uses)	October 2003
	BAS 510 02F Crop		
	BAS 510 02F Turf		
Famoxadone (with cymoxanil fungicide)	Famoxadone Technical	Fungicide for potatoes, tomatoes (2 uses)	May 2003
	Tanos 50DF (with cymoxanil)		
Brassica hirta white mustard seed and sodium α-olefin sulfonate	Exit ISP	Rodenticide for control of Richardson's ground squirrels (1 use)	March 2003
	Exit Concentrate Rodenticide		

Appendix V Summary of Minor Crop Registrations
(1 April 2003 to 31 March 2004)

Minor Uses Registered* (2003–2004)	
Total minor crop uses registered	302
· Food crops	192
· Non-food crops	110
Total reduced-risk uses registered for food uses	92
· Biopesticide uses registered	27

* Through all submission types: joint review, user-requested minor use label expansions, new active ingredients and new uses, and others

Appendix VI Reduced-risk Products Registered
(1 April 2003 to 31 March 2004)

New Reduced-Risk Chemical Active Ingredients Registered	
Chemical	**End-use Product(s)**
Boscalid (BAS 510F)	Lance WDG Fungicide
	Cadence WDG Fungicide
Brassica hirta white mustard seed	Exit Concentrate Insecticide
Sodium ∝-olefin sulfonate	
Fenamidone	Reason 500SC Fungicide
Fluazinam	Allegro 500F Agricultural Fungicide
Trifloxystrobin	Stratego 250EC Fungicide
	Compass 50WG Fungicide
	Flint 50WG Fungicide

New Biopesticide Active Ingredients Registered	
Biopesticide	**End-use Product(s)**
Corn gluten meal	Turfmaize Preemergent Weed Seed Germination Inhibitor
Dried blood	Plantskydd Deer Repellent Soluble Powder Concentrate
	Plantskydd Deer Repellent Pre-Mixed RTU Solution

Appendix VII Emergency Registrations
(1 April 2003 and 31 March 2004)

Name/Registrant	Product Name	Status	Province/Sponsor	Crop	Pest
April 2003					
Bayer Inc.	Check Mite + Bee Hive Pest Control Strip	Granted	Manitoba	Honeybees	Varroa mites
May 2003					
Coulston Products Incorporated	Permethrin Arthropod Repellent Spray	Granted	Military operational deployment abroad	Non-combat military clothing, mosquito netting	Biting arthropods
June 2003					
Gowan Company	Metasystox-R Spray Concentrate Systemic Insecticide	Rejected	British Columbia	Brussel sprouts	Cabbage aphid
BASF Canada Inc.	Headline EC Fungicide	Granted	Ontario	Peas (processing)	Ascochyta
Syngenta Crop Protection Canada Inc.	Ridomil Gold MZ 68WP Fungicide	Granted	Ontario	Ginseng	Phytophthora foliar blight
Syngenta Crop Protection Canada Inc.	Endeavor 50WG Insecticide	Granted	British Columbia	Greenhouse pepper	Aphids
July 2003					
Syngenta Crop Protection Canada Inc.	Matador 120EC Insecticide	Granted	Ontario	Soybean	Soybean aphid
Dow AgroSciences Canada Inc.	Success 480 SC Naturalyte Insect Control Product	Granted	British Columbia	Cane-berry	Variegated cutworm Leafroller
Syngenta Crop Protection Canada Inc.	Endeavor 50wg Insecticide	Granted	Alberta	Greenhouse p epper	Aphids
Syngenta Crop Protection Canada Inc.	Quadris Flowable Fungicide	Granted	Nova Scotia	Spinach	Downy mildew
August 2003					
Engage Agro Corporation	Senator 70WP Systemic Fungicide	Granted	British Columbia, Alberta, Manitoba, Ontario, Quebec, Nova Scotia, New Brunswick, Prince Edward Island	Mushroom	*Trichoderma* green mould
Syngenta Crop Protection Canada Inc.	Matador 120EC Insecticide	Granted	Quebec	Soybean	Soybean aphid
Arvesta Corporation	Decree 50 WDG Fungicide	Withdrawn	British Columbia	Greenhouse lettuce	Grey mould (*botrytis cinerea*)
Bayer CropScience Inc.	Admire 240 Flowable Systemic Insecticide	Granted	Ontario	Highbush blueberry	Japanese beetle, European chafer

Name/Registrant	Product Name	Status	Province/Sponsor	Crop	Pest
September 2003					
Syngenta Crop Protection Canada Inc.	Quadris Flowable Fungicide	Granted	Ontario	Ginseng	Rhizoctonia
Syngenta Crop Protection Canada Inc.	Quadris Flowable Fungicide	Granted	British Columbia	Ginseng	Rhizoctonia
November 2003					
Bayer CropScience Inc.	Merit Solupak Insecticide 75% Wettable Powder	Granted	Ontario	Urban broadleaf trees	Asian longhorned beetle
December 2003					
Coulston Products Incorporated	Permethrin Arthropod Repellent	Granted	Military operational deployment abroad	Non-combat military combat clothing, mosquito netting	Biting arthropods
Coulston Products Incorporated	Insect/arthropod Repellent Protective Treatment for Military Battle Dress Uniform	Granted	Military operational deployment abroad	Non-combat military combat clothing, mosquito netting	Biting arthropods
January 2004					
Bayer CropScience Inc.	Previcur N Aqueous Solution	Granted	Ontario	Greenhouse pepper	Pythium
Syngenta Crop Protection Canada Inc.	Ridomil Gold 480 EC Fungicide	Granted	Br itish Columbia	Greenhouse cucumbers	Pythium
Bayer CropScience Inc.	Intercept 60WP Greenhouse Insecticide	Granted	British Columbia	Greenhouse lettuce	Aphid
February 2004					
Bayer Inc.	CheckMite + Bee Hive Pest Control Strip	Granted	Quebec	Honeybees	Varroa mites
Syngenta Crop Protection Canada Inc.	Cruiser 5FS Seed Treatment Insecticide	Granted	Alberta	Wheat, barley	Wireworm
March 2004					
Nova Scotia Department of Agriculture and Fisheries	Pyrinex 480 EC	Granted	Nova Scotia	Potatoes	Wireworm
Engage Agro Corporation	Senator 70WP Systemic Fungicide	Granted	Ontario and Quebec greenhouses, but the Sponsor is OMAF (documentation for Ontario only)	Tobacco seedlings (greenhouse)	*Rhizoctonia solani* (rhizoctonia damping-off)
New Brunswick	CheckMite + Bee Hive Pest Control Strip	Granted	New Brunswick	Honeybees	Varroa mites
British Columbia	CheckMite + Bee Hive Pest Control Strip	Granted	British Columbia	Honeybees	Varroa mites

Name/Registrant	Product Name	Status	Province/Sponsor	Crop	Pest
March 2004 cont'd					
Makhteshim Aga of North America	Pyrinex 480 EC for Food Crop	Granted	British Columbia	Wireworm	Potato
Engage Agro Corporation	Senator 70WP Systemic Fungicide	Granted	Ontario and Quebec	Tobacco seedlings (greenhouse)	*Rhizoctonia solani* (rhizoctonia damping-off)
Syngenta Crop Protection Canada	Fulfill 50WG Insecticide	Granted	British Columbia	Highbush blueberry	Aphids
FMC Corporation	Command 360 ME	Granted	Quebec	Cucumbers	Weed control
FMC Corporation	Command 360 ME	Granted	Ontario	Cucumbers	Weed control
United Agri Products	Pyrifos 15 G Granular Insecticide	Granted	Nova Scotia	Potatoes	Wireworms
United Agri Products	Pyrifos 15 G Granular Insecticide	Granted	British Columbia	Potatoes	Wireworms
Bayer Inc.	CheckMite + Bee Hive Pest Control Strip	Granted	Ontario	Honeybees	Varroa mites
Bayer Inc.	Folicur 432 F Foliar Fungicide	Granted	Manitoba	Wheat	Fusarium head blight (scab)
Syngenta Crop Protection Canada	Ridomil Gold 480 EC	Granted	Ontario	Greenhouse cucumbers	Pythium
British Columbia Ministry of Agriculture, Food and Fisheries	Furadan 480 F (Carbofuran)	Granted	British Columbia	Turnips and rutabagas	Cabbage root maggot

Appendix VIII MRLs Published
(1 April 2003 and 31 March 2004)

Total number published: 158*

Project No.	Common Name	MRL (ppm)	Food	No. of MRLs
Final MRLs published in *Canada Gazette*, Part II				
1151	S-metolachlor including its metabolites	0.3	Dry beans, lima beans, peas, snap beans	26
		0.2	Kidney of cattle, potatoes, soybeans	
		0.1	Apples, apricots, cherries, corn, peaches/nectarines, pears, plums, rutabagas, sugar beets, tomatoes	
		0.05	Liver of cattle and poultry	
		0.02	Eggs, meat of cattle, goats, hogs poultry and sheep, milk	
1214	Cyhalothrin-lambda	0.15	Corn flour	3
		0.1	Tomatoes	
		0.05	Corn	
1313	Thiamethoxam including its metabolite	0.02	All food crops	1
1315	Fosetyl-aluminum	60	Bok choy cabbage, Chinese broccoli	2
1326	Methoxyfenozide	1.5	Apples, crabapples, loquats, mayhaws, pears, oriental pears, quinces	32
		0.1	Fat, kidney, liver, meat and meat by-products of cattle, goats, hogs, horses and sheep	
	Methoxyfenozide including its metabolite	0.1	Kidney and liver of cattle, goats, hogs, horses and sheep	
1328	Fenhexamid	20	Blackberries, loganberries, raspberries	3
1331	Permethrin	0.5	Wasabi	1
1333	Thifensulfuron-methyl	0.07	Tomatoes	1
1335	Nicosulfuron	0.05	Blueberries	1
1340	Imidacloprid including its metabolites	3	Sour cherr ies, sweet cherries	3
		1	Blueberries	
1345	Metalaxyl including its metabolites	0.05	Barley	1
1348	Glyphosate including the metabolite AMPA	10	Sugar beets	1
			Total final MRLs	75*
Proposed MRLs published in the *Canada Gazette*, Part I				
1151	S-metolachlor including its metabolites	0.3	Dry beans, lima beans, peas, snap beans	26
		0.2	Kidney of cattle, potatoes, soybeans	
		0.1	Apples, apricots, cherries, corn, peaches/nectarines, pears, plums, rutabagas, sugar beets, tomatoes	
		0.05	Liver of cattle and poultry	
		0.02	Eggs, meat of cattle, goats, hogs poultry and sheep, milk	
1315	Fosetyl-aluminum	60	Bok choy cabbage, Chinese broccoli	2

Project No.	Common Name	MRL (ppm)	Food	No. of MRLs
1336	Rimsulfuron	0.05	Blueberries	1
1338	Kresoxim-methyl including its metabolites	0.5	Crabapples, loquats, mayhaws, oriental pears, pears, quinces	7
		0.15	Pear juice	
1339	Spinosad	0.1	Apples	2
		0.02	Potatoes	
1344	Difenoconazole	0.05	Mustard seed	3
		0.03	Rapeseed (canola)	
		0.01	Barley	
1345	Metalaxyl including its metabolites	0.05	Barley	1
1348	Glyphosate including the metabolite AMPA	10	Sugar beets	1
1354	Picolinafen	0.05	Barley, wheat	2
1362	Bentazon including its metabolites	0.05	Flax	1
1371	Fludioxonil	7	Green onions	4
		2	Strawberries	
		1	Grapes	
		0.2	Dry bulb onions	
1372	Trimethylsulfonium cation	13	Soybeans	22
		1.5	Lentils	
		1	Kidney of cattle, goats, hogs, horses and sheep	
		0.5	Meat and meat by-products of cattle, goats, hogs, horses and sheep, milk	
		0.1	Kidney and liver of poultry	
		0.05	Meat of poultry	
		0.02	Eggs	
1377	Foramsulfuron	0.01	Field corn grain	1
1378	Fluzifop-butyl	0.1	Blueberries	1
1382	Pyrimethanil	0.05	Bananas	1
1387	Cyhalothrin-lambda	0.15	Leeks	1
			Total proposed MRLs	76
IMAs published in the *Canada Gazette*, Part I				
1396	Fenhexamid	1	Tomatoes	1
1396	Fenhexamid	23	Lettuce	2
		4	Bushberries	
1391	Propiconazole including its metabolites	0.7	Blackberries, loganberries, raspberries	3
1387	Cyhalothrin-lambda	0.15	Leeks	1
			Total MRLs published in the 4 IMAs	7

* The total number includes a count of "1" for thiamethoxam (1313) in "all food crops".

Appendix IX Published Re-evaluation
(1 April 2003 to 31 March 2004)

Discontinued Active Ingredients (23)

2,4-D (sodium salt)

Mixture of BCD + DDH + DDM

Difenzoquat

Ethoxyquin

Flamprop-m-methyl

Monolinuron

N-alkyl dimethyl benzyl ammonium chloride

Poly(hydroethylene[dimethylimino]ethylene[dimethylimino] methylenedichloride

Potassium dichromate

Pyridate

Sodium metaborate tetrahydrate

Allethrin mixed isomer products

Azaconazole

Bendiocarb

Chinomethionat

Lavender

Mecoprop—3 active ingredient forms

Oxydemeton-methyl

Pindone present in free form or as sodium salt

Propargite

S-(2-ydroxypropyl)thiomethane Sulfonate

Active Ingredients Being Phased-out as a Result of PMRA Review (2)

Azinphos-methyl

Terbufos

Active Ingredients Approved for Continuing Registration with Label Modifications

Final Decisions (2)

Methyl bromide

(Z)-9-tricosene[1]

Proposed Decisions (7)

(Z)-9-tricosene[1]

Ancymidol

Fenitrothion

Hydramethylnon

Methyl bromide

Polybutene

Putrescent whole egg solids

Active Ingredients Approved for Continuing Registration Without Modification (2)

Pheromone: Codling moth

Pheromone: Grape berry moth (9-dodecenyl acetate)

1 Two decisions were reached on this chemical.

Appendix X
Notices of Violation Issued
(1 April 2003 to 31 March 2004)

Violations Related to Use

Howard Huy Farms Ltd., Leamington, Ontario. Residues detected on samples of greenhouse cucumbers resulting in one penalty issued.

John Dipietro, Leamington, Ontario. Residues detected on samples of greenhouse cucumbers resulting in one penalty issued.

Rivers Airspray, Rivers, Manitoba. Aerial application of a fungicide resulting in one penalty issued.

Kevin Mooney, Lloydminster, Saskatchewan. Aerial application of a fungicide resulting in one warning issued.

Conceicao Farms Inc., Keswick, Ontario. Propachlor and metolachlor residues in onion field soil sample resulting in one warning issued.

Robert Boutin, St-Renee-de-Beauce, Quebec. Use of PFH tablets in maple syrup production resulting in one penalty issued.

Santes Enterprises Ltd. A/O Acadia Lawn & Tree Spraying, Dieppe, New Brunswick. Use inconsistent with label (pyrate on residential lawn) resulting in one warning issued.

Bihun Farms Ltd., Leamington, Ontario. Investigation into the use of an unregistered herbicide on onions resulting in one warning issued.

Tegart Apiaries Ltd., Fairview, Alberta. Bee keepers misuse of a product resulting in one warning issued.

Wolfe Honey Co., Falher, Alberta. Not following label restrictions with regard to the use of a product resulting in one warning issued.

Townline Growers (1994) Ltd., Abbotsford, British Columbia. Positive sample for bifenthrin on raspberries resulting in one warning issued.

Violations Related to Advertising

Bayer Cropscience Inc., Calgary, Alberta. Advertisement containing off label uses resulting in three penalties issued.

Violations Related to Sale

Zodiac Pool Care Canada, Oakville, Ontario. Sale of unregistered pool chlorinating device resulting in one penalty issued.

Roy Kiss, doing business as Nature's Own, Port Alberni, British Columbia. Insect repelling wrist band found advertised for sale in Ottawa resulting in one penalty issued.

Sherley's Canada Inc., Nanaimo, British Columbia. Unregistered animal repellents being sold resulting in one warning issued.

Violation Related to Importation

Rose-A-Lea Gardens Ltd., Mt. Brydges, Ontario. Importation of unregistered control products resulting in one penalty issued.

Appendix XI Documents Released by the Pest Management Regulatory Agency
(1 April 2003 to 31 March 2004)

Re-evaluation Note (REV) Series	
Control Number	**Document Name**
REV2004-01	Update on the Re-evaluation of CCA Heavy Duty Wood Preservative
REV2003-09	Update on the Re-evaluation of Heavy Duty Wood Preservative Creosote
REV2003-08	PMRA Re-evaluation Program Workplan (April 2003–June 2004)
REV2003-07	Update on CCA
REV2003-06	Update on Re-evaluation of Carbaryl in Canada
REV2003-05	Pest Control Products Under Re-evaluation: Discontinuation of Agricultural Products Registered Under the *Pest Control Products Act* and Proposed Changes to Maximum Residue Limits Under the *Food and Drugs Act*
REV2003-04	Pest Control Products Under Re-evaluation: Discontinuation of non-agricultural products registered under the *Pest Control Products Act*
REV2003-03	Re-evaluation of Malathion: Assessment of Use in Mosquito Abatement Programs
Proposed Acceptability for Continuing Registration (PACR) Series [re-evaluation]	
Control Number	**Document Name**
PACR2004-03	Re-evaluation of Polybutene
PACR2004-02	Re-evaluation of Putrescent Whole Egg Solids
PACR2004-01	Re-evaluation of Ancymidol
PACR2003-13	Re-evaluation of Atrazine
PACR2003-12	Re-evaluation of (Z)-9-tricosene
PACR2003-11	Re-evaluation of Hydramethylnon
PACR2003-10	Re-evaluation of Malathion
PACR2003-09	Re-evaluation of Tetrachlorvinphos
PACR2003-08	Re-evaluation of Fenitrothion
Re-evaluation Decision Document (RRD) Series	
Control Number	**Document Name**
RRD2004-06	Re-evaluation of (Z)-9-tricosene
RRD2004-05	Azinphos-methyl
RRD2004-04	Re-evaluation of Terbufos
RRD2004-03	Re-evaluation of 9-dodecenyl Acetate
RRD2004-02	Re-evaluation of Codling Moth Pheromone
RRD2004-01	Re-evaluation of Methyl Bromide
Regulatory Note (REG) Series [new pesticides]	
Control Number	**Document Name**
REG2004-05	Ophiostoma piliferum Strain D97 Sylvanex Technical (TGAI) Sylvanex (EP)
REG2004-04	Iodosulfuron-methyl-sodium
REG2004-03	Trifloxystrobin
REG2004-02	Boscalid/BAS 510
REG2004-01	PMRA List of Formulants
REG2003-12	Fluazinam
REG2003-11	Fenamidone Technical Fungicide, Reason 500 SC Fungicide
REG2003-10	Famoxadone/Tanos 50DF
REG2003-09	Corn Gluten Meal
REG2003-08	Foramsulfuron Technical Herbicide, Option 2.25 SC Herbicide, and Option 35 DF Herbicide
REG2003-07	BioSafe OxiDate Bactericide/Fungicide Potato Storage Treatment containing Hydrogen Peroxide
REG2003-06	Pyraclostrobin Headline EC Cabrio EG

Regulatory Note (REG) Series [new pesticides]	
Control Number	**Document Name**
REG2003-05	Imiprothrin
REG2003-04	EXIT™ ISP
REG2003-03	Fenbuconazole
Proposed Regulatory Decision Documents (PRDD) Series [new pesticides]	
Control Number	**Document Name**
PRDD2004-01	TepraloxydimEquinox EC Dash HC
Regulatory Decision Document (RDD) Series [new pesticides]	
Control Number	**Document Name**
RDD2004-01	Kaolin / Surround WP Crop Protectant
RDD2003-10	*Streptomyces griseoviridis* strain K61
RDD2003-09	Fenhexamid
RDD2003-08	Isomate-M 100 Oriental Fruit Moth Pheremone
RDD2003-07	Flufenacet
RDD2003-06	Lambda-Cyhalothrin Demand CS Insecticide
RDD2003-05	3M Sprayable Pheromone for Mating Disruption of Tomato Pinworm
RDD2003-04	Kresoxim-methyl
RDD2003-03	Dried Blood
Regulatory Proposal (PRO) Series	
Control Number	**Document Name**
PRO2003-02	Data Requirements and Labelling for Oilseed Oriental Mustard [*Brassica juncea* (L.)]
Regulatory Directive (DIR) Series	
Control Number	**Document Name**
DIR2004-01	Formulants Program
DIR2003-04	Efficacy Guidelines for Plant Protection Products
DIR2003-03	Harmonization of environmental chemistry and fate data requirements for chemical pesticides under NAFTA
DIR2003-02	Harmonization of Regulation of Pesticide Seed Treatment in Canada and the United States
DIR2003-01	Organizing and Formatting a Complete Submission for Pest Control Products
Science Policy Notice (SPN) Series	
Control Number	**Document Name**
SPN2003-05	Guidance for Refining Anticipated Residue Estimates for Use in Acute Dietary Probabilistic Risk Assessment
SPN2003-04	General Principles for Performing Aggregate Exposure and Risk Assessments
SPN2003-03	Assessing Exposure from Pesticides in Food - A User's Guide
SPN2003-02	Assigning Values to Nondetected/Nonquantified Pesticide Residues in Food
SPN2003-01	Choosing a Percentile of Acute Dietary Exposure as a Threshold of Concern
Discussion Document (DIS) Series	
Control Number	**Document Name**
DIS2003-05	Preliminary Consultation on a Regulation respecting Reconsideration of Registration Decisions
DIS2003-04	Preliminary Consultation on Proposed Sales Reporting Regulation
DIS2003-03	Pesticides Adverse Effects Reporting Regulation
DIS2003-02	Preliminary Consultation on a Proposal to Implement Elements of WHMIS for Pest Control Products
Update on Registrations for Minor Crops and Uses (MCU) Series [previously known as the URMULE Update (URL) Series]	
Control Number	**Document Name**
MCU2004-01	Update on Registrations for Minor Crops and Uses
URL2003-02	User Requested Minor Use Label Expansion Program Registrations for April 1–April 30, 2003
URL2003-01	User Requested Minor Use Label Expansion Program Registrations for September 1, 2002 – March 31, 2003
NAFTA-Joint Review (NAFTA-JR) Series	
Control Number	**Document Name**
JR2004-01	Status of NAFTA Joint Reviews (JR) USEPA, Canadian PMRA and Mexico CICOPLAFEST

Appendix XII Websites

The following is a listing of websites referenced in this annual report.

Pest Management Regulatory Agency

www.pmra-arla.gc.ca

The PMRA's website contains all current PMRA publications and a wide range of information for industry and the general public.

Pest Management Regulatory Agency—Minor Crops and Uses

www.pmra-arla.gc.ca/english/pubs/minorcrops-e.html

For additional information on minor crops and uses in Canada.

Pest Control Products Act

http://laws.justice.gc.ca/en/P-9.01/92455.html

For the new Pest Control Products Act.

Pest Management Advisory Council

www.pmra-arla.gc.ca/english/advbod/pmac-e.html

For information on the Pest Management Advisory Council and its activities.

Economic Management Advisory Council

www.pmra-arla.gc.ca/english/advbod/emac-e.html

For information on the Economic Management Advisory Council and its activities.

Federal/Provincial/Territorial Committee on Pest Management and Pesticides

www.pmra-arla.gc.ca/english/fpt/fpt-e.html

For information on the FPT Committee, its working groups and its activities.

Working Group on Pesticide Education, Training and Certification

www.pmra-arla.gc.ca/english/fpt/edutran-e.html

For more information on pesticide education, training and certification in Canada.

Healthy Lawns website

www.HealthyLawns.net

For information on reduced-risk pest management and pest prevention strategies for lawn and turfgrass for gardeners, lawn care service providers and green space professionals

Globally Harmonized System of Classification and Labelling of Chemicals

www.hc-sc.gc.ca/ahc-asc/intactiv/ghs-sgh/index_e.html

For additional information on the GHS in Canada.

GHS Pesticides Sectoral Working Group

www.hc-sc.gc.ca/ahc-asc/intactiv/ghs-sgh/com/pest-parasite/notes/index_e.html

For additional information on this working group and its terms of reference.

Health Canada, Office of Sustainable Development

www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hecs-dgsesc/osd-bdd/index_e.html

For more details about current and previous sustainable development strategies.

Becoming the Change We Wish to See

www.hc-sc.gc.ca/ahc-asc/pubs/sus-dur/index_e.html

For more information on Health Canada's Sustainable Development Strategy 2004–2007.

Standing Committee on the Environment and Sustainable Development

www.parl.gc.ca

Additional information on this standing committee as well as the report *Pesticides: Making the Right Choice for the Protection of Health and the Environment.*

United States Environmental Protection Agency

www.epa.gov

For information on the USEPA as well as environmental and pest control product issues in the United States. The following USEPA documents are available on the USEPA website.

Supplemental Guidance for Assessing Cancer Susceptibility from Early-Life Exposure to Carcinogens

Choosing a Percentile of Acute Dietary Exposure as a Threshold of Regulatory Concern (16 March 2000)

Available Information on Assessing Exposure from Pesticides in Food—A User's Guide (21 June 2000)

General Principles for Performing Aggregate Exposure and Risk Assessments (28 November 2001)

Guidance for Refining Anticipated Residue Estimates for Use in Acute Dietary Probabilistic Risk Assessment (15 June 2000)

www.epa.gov/pesticides/cumulative/rra-op/

For more information on the USEPA's revised cumulative risk assessment of organophosphate pesticides.

North American Free Trade Agreement Technical Working Group on Pesticides

www.pmra-arla.gc.ca/english/intern/twg-e.html

For more information on the Technical Working Group on Pesticides as well as their projects, initiatives and accomplishments.

www.pmra-arla.gc.ca/english/pdf/nafta/risk/rr_pulsecrops-e.pdf

For a description of the NAFTA pulse risk-reduction project to address issues being faced by the pulse industry in North America.

NAFTA Documents

North American Free Trade Agreement Technical Working Group on Pesticides 5-Year Strategy
www.pmra-arla.gc.ca/english/pdf/nafta/docs/naftatwg_5yearstrategy-e.pdf

North American Free Trade Agreement Technical Working Group on Pesticides Workplan
www.pmra-arla.gc.ca/english/pdf/nafta/docs/naftatwg_workplan-e.pdf

NAFTA Guidance Document on Data Requirements for Tolerances on Imported Commodities
www.pmra-arla.gc.ca/english/pdf/nafta/naftajr/nafta-jr2003-02-e.pdf

Organisation of Economic Co-operation and Development

Guidance on formats for submissions may be found on the OECD website www.oecd.org/, at www.eddenet.ca and through links via the PMRA website www.pmra-arla.gc.ca

Harmonisation of Environmental Emission Scenarios: An Emission Scenario Document for Antifouling Products in OECD Countries

http://ecb.jrc.it/Documents/Biocides/ENVIRONMENTAL_EMISSION_SCENARIOS/PT_21_antifouling_products.pdf

Canadian Horticultural Council

www.hortcouncil.ca

For additional information about the Council and Integrated Fruit Production or to obtain a copy of *Integrated Fruit Production Guidelines for Apple Orchards in Canada.*

Canola Council of Canada

www.canola-council.org

For information on the Canola Council of Canada, canola oil and its uses, growing canola and the Canadian canola industry.

Appendix XIII PMRA Documents

The following is a listing of PMRA documents referenced in this annual report.

Discussion Documents

DIS2003-01

Revocation of the 0.1 ppm General Maximum Residue Limit for Food Pesticide Residues [Regulation D.15.002(1)]
www.pmra-arla.gc.ca/english/pdf/dis/dis2003-01-e.pdf

DIS2003-02

Preliminary Consultation on a Proposal to Implement Elements of WHMIS for Pest Control Products
www.pmra-arla.gc.ca/english/pdf/dis/dis2003-02-e.pdf

DIS2003-03

Pesticides Adverse Effects Reporting Regulation
www.pmra-arla.gc.ca/english/pdf/dis/dis2003-03-e.pdf

DIS2003-04

Preliminary Consultation on Proposed Sales Reporting Regulation
www.pmra-arla.gc.ca/english/pdf/dis/dis2003-04-e.pdf

DIS2003-05

Preliminary Consultation on a Regulation respecting Reconsideration of Registration Decisions
www.pmra-arla.gc.ca/english/pdf/dis/dis2003-05-e.pdf

Regulatory Directives

DIR99-06

Voluntary Pesticide Resistance-Management Labelling Based on Target Site/Mode of Action
www.pmra-arla.gc.ca/english/pdf/dir/dir9906-e.pdf

DIR97-02

Guidelines for the Research and Registration of Pest Control Products Containing Pheromones and Other Semiochemicals
www.pmra-arla.gc.ca/english/pdf/dir/dir9702-e.pdf

DIR2001-01

User Requested Minor Use Label Expansion
www.pmra-arla.gc.ca/english/pdf/dir/dir2001-01-e.pdf

DIR2001-03

PMRA Re-evaluation Program
www.pmra-arla.gc.ca/english/pdf/dir/dir2001-03-e.pdf

DIR2001-05

Registration of Pesticides for Emergency Use
www.pmra-arla.gc.ca/english/pdf/dir/dir2001-05-e.pdf

DIR2002-02

The PMRA Initiative for Reduced-Risk Pesticides
www.pmra-arla.gc.ca/english/pdf/dir/dir2002-02-e.pdf

DIR2003-02

Harmonization of Regulation of Pesticide Seed Treatment in Canada and the United States
www.pmra-arla.gc.ca/english/pdf/dir/dir2003-02-e.pdf

DIR2003-03

Harmonization of environmental chemistry and fate data requirements for chemical pesticides under NAFTA
www.pmra-arla.gc.ca/english/pdf/dir/dir2003-03-e.pdf

DIR2003-04

Efficacy Guidelines for Plant Protection Products
www.pmra-arla.gc.ca/english/pdf/dir/dir2003-04-e.pdf

DIR2004-01

Formulants Program
www.pmra-arla.gc.ca/english/pdf/dir/dir2004-01-e.pdf

Re-evaluation Decision Document

RRD2004-01

Re-evaluation of Methyl Bromide
www.pmra-arla.gc.ca/english/pdf/rrd/rrd2004-01-e.pdf

Re-evaluation Note

REV2003-08

PMRA Re-evaluation Program Workplan (April 2003–June 2004)
www.pmra-arla.gc.ca/english/pdf/rev/rev2003-08-e.pdf

Regulatory Note

REG2002-04

Category C Submission Efficacy Reviews
www.pmra-arla.gc.ca/english/pdf/reg/reg2002-04-e.pdf

REG2004-01

PMRA List of Formulants
www.pmra-arla.gc.ca/english/pdf/reg/reg2004-01-e.pdf

Regulatory Proposal

PRO-9601

Management of Submissions Policy
www.pmra-arla.gc.ca/english/pdf/pro/pro9601-e.pdf

PRO2002-02

Guidelines for the Research and Registration of Pest Control Products Containing Pheromones and Other Semiochemicals
www.pmra-arla.gc.ca/english/pdf/pro/pro2002-02-e.pdf

PRO2003-01

Estimating the Water Component of a Dietary Exposure Assessment
www.pmra-arla.gc.ca/english/pdf/pro/pro2003-01-e.pdf

Science Policy Note

SPN2001-01

Guidance for Identifying Pesticides that have a Common Mechanism of Toxicity for Human Health Risk Assessment
www.pmra-arla.gc.ca/english/pdf/spn/spn2001-01-e.pdf

SPN2003-01

Choosing a Percentile of Acute Dietary Exposure as a Threshold of Concern
www.pmra-arla.gc.ca/english/pdf/spn/spn2003-01-e.pdf

SPN2003-02

Assigning Values to Nondetected/Nonquantified Pesticide Residues in Food
www.pmra-arla.gc.ca/english/pdf/spn/spn2003-02-e.pdf

SPN2003-03

Assessing Exposure from Pesticides in Food: A User's Guide
www.pmra-arla.gc.ca/english/pdf/spn/spn2003-03-e.pdf

SPN2003-04

General Principles for Performing Aggregate Exposure and Risk Assessments
www.pmra-arla.gc.ca/english/pdf/spn/spn2003-04-e.pdf

SPN2003-05

Guidance for Refining Anticipated Residue Estimates for Use in Acute Dietary Probabilistic Risk Assessment
www.pmra-arla.gc.ca/english/pdf/spn/spn2003-05-e.pdf

Update on Registrations for Minor Crops and Uses

www.pmra-arla.gc.ca/english/pubs/mcu-e.html

Risk Reduction Projects

Overview: Integrated Pest Management of Sea Lice in Salmon Aquaculture
www.pmra-arla.gc.ca/english/pdf/spm/spm2003-e.pdf

Fact Sheet on Integrated Pest Management of Sea Lice in Salmon Aquaculture
www.pmra-arla.gc.ca/english/pdf/fact/fs_ipmsealice-e.pdf

Eastern Canada Cranberry IPM Manual
www.pmra-arla.gc.ca/english/pdf/spm/ipmcranberries-e.pdf

PMRA ARLA

Pest Management Regulatory Agency

Health Canada Santé Canada

Canada